Award Number: W81XWH-12-1-0549

TITLE: Double-Blind, Randomized Study of Safety and Efficacy of OnabotulinumtoxinA (OnaBoNT-A) versus Oral Oxybutynin in SCI Patients with NDO (11-09-10-04)

PRINCIPAL INVESTIGATOR: Christopher P. Smith, MD

CONTRACTING ORGANIZATION: Baylor College of Medicine, Houston, TX 77030

REPORT DATE: October 2014

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
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1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
Oct2014	Annual	30 Sep 2012 - 29 Sep 2014

4. TITLE AND SUBTITLE

A Double-Blind, Randomized Study of Safety and Efficacy of OnabotulinumtoxinA (OnaBoNT-A) versus Oral Oxybutynin in SCI Patients with NDO (11-09-10-04)

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-12-1-0549

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Christopher P. Smith, MD

E-Mail: cps@bcm.edu

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Baylor College of Medicine
One Baylor Plaza, T100
Houston, TX 77030-3498

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

No subjects have been treated as yet. Recruitment at Michael E. DeBakey VAMC has been difficult due to eligibility criteria. Dr. Smith has completed the application to open patient recruitment to a new site with a large spinal cord injury population, The Institute of Rehabilitation and Research (TIRR). He has just become credentialed and the IRB process will begin immediately. Enrollment will begin as quickly as possible.

15. SUBJECT TERMS
Botulinum Toxin, Oxybutynin, Overactive Bladder, Spinal Cord Injury, Urinary Incontinence, Nerve Growth Factor, Urine Biomarkers

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
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Annual Report for W81XWH-12-1-0549 SC110198:
A Double-Blind, Randomized Study of Safety and Efficacy of OnabotulinumtoxinA (OnaBoNT-A) versus Oral Oxybutynin in SCI Patients with NDO (11-09-10-04)

INTRODUCTION

This is a Phase 3B, double-blind, randomized, placebo-controlled, parallel-group study to assess the safety and efficacy of onaBoNT-A or 15 mg per day of oral oxybutynin hydrocholoride ER in 36 spinal cord injured veterans who visit the Michael E. DeBakey Veterans Affairs Medical Center (MEDVAMC) in Houston, TX and are diagnosed with neurogenic detrusor overactivity. Volunteers will include both males and females who are 18 to 80 years of age. There are no eligibility restrictions as to race or ethnicity.

KEYWORDS

Botulinum Toxin, Oxybutynin, Overactive Bladder, Spinal Cord Injury, Urinary Incontinence, Nerve Growth Factor, Urine Biomarkers

OVERALL PROJECT SUMMARY

Previously, one patient was consented but did not respond to repeated attempts to contact him to set his screening visit appointment. He is considered lost to follow-up.

The protocol received continuing BCM IRB approval on April 10, 2014. An amendment to allow brochures to be distributed during the MEDVAMC Research Week was approved on April 21, 2014. An amendment to allow the use of the revised HIPAA Authorization form is undergoing IRB review that is scheduled for 10/22/14.

This past year, 130 charts were reviewed and discuss in SCI Rounds. Theses patient where not eligible for our study due to the following:

- 30 patients do not met Inclusion #6
- 22 patients do not met Inclusion #7
- 28 patients do not met Inclusion #10
- 20 patients do not met Inclusion #11
- 3 patients met Exclusion #1
- 1 patient Exclusion #2
- 1 patient chart states not interested in getting Botox
- 1 patient chart cannot tolerate Oxybutynin
- 1 patient chart says Botox did not work for this patient
- 1 patient chart says Oxybutynin causes patient to have difficulty swallowing
- 1 patient chart says he has behavior issues
- 3 patients were interested in study but they are non-veterans
- 18 patients' charts indicate non-Texas residents

KEY RESEARCH ACCOMPLISHMENTS: Nothing to report

CONCLUSIONS

Dr. Smith has completed the application to open patient recruitment to a new site with a large spinal cord injury population, The Institute of Rehabilitation and Research (TIRR). He has just become credentialed and the IRB process will begin immediately. Enrollment will begin as quickly as possible.

PUBLICATIONS ABSTRACTS AND PRESENTATIONS: None

INVENTIONS, PATENTS AND LICENSES: None

REPORTABLE OUTCOMES: None

OTHER ACHIEVEMENTS: None

REFERENCES: None

APPENDICES

- IRB renewal submission: 03/03/14
- IRB Annual Approvals: 04/21/14
  - Letter
  - Informed Consent Document
- Questionnaires
  - Incontinence Quality of Life Instrument Neurogenic Module
  - Incontinence Quality of Life Instrument (I-QOL)
  - OAB-Patient Satisfaction with Treatment Questionnaire (OAB_PSTQ)
  - Patient Global Assessment (PGA)
- Diaries
  - Pill
  - Urine
- CV: 09-02-14

QUADCHART: Attached

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

RENEWAL

Protocol Number: H-26296
Principal Investigator: CHRISTOPHER PATRICK SMITH
Initial Submit Date: 05/24/2012
Renewal Submit Date: 03/03/2014
Protocol Title: A DOUBLE-BLIND, RANDOMIZED STUDY OF THE SAFETY AND EFFICACY OF ONABOTULINUMTOXINA (ONABONT-A) VERSUS ORAL OXYBUTYNIN IN SPINAL CORD INJURED PATIENTS WITH NEUROGENIC DETRUSOR OVERACTIVITY (PROTOCOL NUMBER 11-09-10-04)

SUBJECTS

During your last approval period, you were approved to enroll 36 subjects locally and 36 subjects worldwide.

Race/Ethnicity	Male	Female
All Ethnicities	1	0
American Indian Or Alaskan Native	0	0
Asian/Non Vietnamese	0	0
Black Or African American	0	0
Hispanic Or Latino	0	0
Mixed Race Or Ethnicity	0	0
Native Hawaiian Or Pacific Islander	0	0
Vietnamese	0	0
White	0	0

LOCAL: 1
WORLDWIDE: 1

MONITORED

If the study was monitored during the last approval period, please indicate by whom and provide a brief description of the findings:
Not Applicable

PROTOCOL STATUS

If the study will not be open to recruitment during the next approval period, indicate why the study should remain open:
Not Applicable

NEW INFORMATION

I am aware of no new information that might effect a subject's willingness to continue participating in this study.

GENERAL SUMMARY

The subject was entered onto the master list of subjects for the study signed a consent form prior to undergoing any study interactions or interventions, unless the IRB has granted a waiver of consent or a waiver of documentation of consent. None of these subjects are considered members of vulnerable populations. We have not had any adverse events, unanticipated problems involving risks to subjects or others; therefore, there were no SAEs (whether related or unrelated to the research) reported to the IRB. A total of 1 subject has signed an informed consent document for this study. He has not responded to requests to make an appointment for the screening visit. A certified letter was mailed to him, but was not returned. The subject has been withdrawn from the study. Recruitment has been difficult for this population. Two hundred and fifty-seven (257) letters were mailed out to SCI patients that were previously seen in the VA clinics. Results: 11 called to discuss the study. Of those 11, 8 did not meet eligibility because 5 were not experiencing leakage, 2 had stress incontinence, and 1 patient did not have SCI at all. Of the 3 that qualified: 1 lived to far to be in this study, 1 declined to participate once the study was explained to wife, and 1 declined because he didn't want to CIC. 6 letters were returned due to outdated addresses with no forwarding addresses. One letter was received stating that the patient was deceased. Four patients responded to the flyers posted in the clniics. Results: 1 had total incontinence, 1 was planning to move to Louisiana but if he did not, he would call back in new year, and 1 is a cocaine user. 1) We are attending a weekly SCI Urology meeting to directly interact with PMR staff regarding potential study candidates. 2) We are also manually reviewing the entire SCI database to identify local patients we will then attempt to directly contact by phone to inquire about their interest in our study.

RISK/BENEFIT RATIO

EVENTS
No Events have been reported.

EXCEPTIONS
No Exceptions have been reported.

DEVIATIONS
No Deviations have been reported.

AMENDMENTS (As of: 6/9/2014 10:08:51 AM) (Sort Order: Amendment Date)

Amendment Submit Date:	04/14/2014
Reason:	Other Amendment
Description:	Approval of already approved brochure so it can be used at MEDVAMC Research Week. Section J2 reads, 'Brochures may be placed in the clinic area to help draw attention to the clinical research study.' It has been edited to include, 'The brochures will be used a posters during the MEDVAMC Research Week.'

Amendment Submit Date:	11/20/2013
Reason:	Multiple Amendments
Description:	1. Informed consent has been revised to remove unneccessary spaces and language. There appears to be a 'period' in the printed (or print view) that is not appropriate. We are not able to remove it. 2. The DOD has requested that the sentence regarding the study's sponsor by revised. This sentence is at the end of the Background section. 3. All advertising has been revised to indicate the study coordinator's new telephone number at the VA and replacing of the BCM logo.

Amendment Submit Date:	11/01/2013
Reason:	Other Amendment
Description:	Addition of PHI being collected in order to provide the subjects' stipends. Sections H, L and Qj have been revised.

Amendment Submit Date:	07/05/2013
Reason:	Multiple Amendments
Description:	Protocol v. 6/12/13 Protocol Changes from 4-30-13 to 6-12-13 Purpose – page 15 Was: At baseline, each follow-up period, and after a two week washout period, urine will be collected for analysis of biomarkers for nerve growth factor (NGF) and chemokines/cytokines to determine the potential role of urine biomarkers as patient selection and surrogate endpoints of treatment outcome predictors. Now: At baseline and each follow-up period, urine will be collected for analysis of biomarkers for nerve growth factor (NGF) and chemokines/cytokines to determine the potential role of urine biomarkers as patient selection and surrogate endpoints of treatment outcome predictors. Clarification of detrusor overactivity: Eligibility – Inclusion #7, page 17 Was: Volunteer has detrusor overactivity (defined as a phasic rise in bladder pressure during the filling phase determined by urodynamics) demonstrated during the screening period or Day 1 (prior to randomization, or if within 3 months of screening if patient is off antimuscarinic/anticholinergic drugs at the time of urodynamic testing). Now: Volunteer has detrusor overactivity (defined as a phasic rise in bladder pressure during the filling phase determined by urodynamics) demonstrated during the screening period or within 6 months of screening if patient is off antimuscarinic/ anticholinergic drugs at the time of urodynamic testing). Recruitment Process, page 19 Advertising brochures will be placed in the Urology Clinic; included in the MEDVAMC newsletter; and included in a mail out planned for potential subjects. An advertisement will be placed on the Craig's List website. Study Procedures 10.1 Screening - Visit 1, page 19

Was: Urodynamic studies: Now: Urodynamic studies (if not performed 6 months prior to the Randomization Visit): 10.3 Post Randomization/Treatment Visits (Follow Up), page 23 Was: Post Randomization/Treatment Visits (Follow Up) (Day 3 (± 3 days) weeks, and 6, 9, 12, 18, 24, and 26 months post randomization/treatment) Now: Post Randomization/Treatment Visits (Follow Up) -Day 3, and Weeks 4, 12, and 24 (± 3 days) post randomization/treatment 10.3.2 Visit 4, page 23 Was: Visits 4, 5, and 7: Weeks 4, 8, and 16 (± 3 days) post randomization/treatment Now: Week 4 (± 3 days) post randomization/treatment 10.3.3. Visit 5, page 23 Was: Visit 6: Week 12 (± 3 days) post randomization/treatment Now: Visit 5: Week 12 (± 3 days) post randomization/treatment 10.3.4. Visit 8 Week 20 (± 3 days) post randomization/treatment, page 23 Deleted study visit 10.3.5. End of Study Visit, page 23 Was: Visit 10: Week 26 (± 3 days) post Visit 9 - End of Study Visit Now: Visit 6: Week 24 (± 3 days) post randomization/treatment - End of Study Visit Was: Urodynamic studies no longer required at End of Study Visit Now: Urodynamic studies no longer required at End of Study Visit CMP (Complete Metabolic Panel) has been added. Data Analysis, page 24 Was: Additionally, we will look at the longitudinal pattern of the questionnaires at baseline, 4, 8 and 12 weeks…. Now: Additionally, we will look at the longitudinal pattern of the questionnaires at baseline, 4, and 12 weeks…. Subject Stipend Section 17: Withdrawal from Study, page 32 Was: Volunteers participating in this study will not receive any payment for their participation. Now: Volunteers participating in this study will receive $50 for completing each of the study visits 2, 4, 5, and 6. Schedule of Events: Appendix I, page 41 Advertising: BCM website revision, Brochure, Patient Letter, and Craig's List ad

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Amendment Submit Date: 07/05/2013
Reason: Protocol no longer actively enrolling
Description: Protocol v. 6/12/13 Protocol Changes from 4-30-13 to 6-12-13 Purpose – page 15 Was: At baseline, each follow-up period, and after a two week washout period, urine will be collected for analysis of biomarkers for nerve growth factor (NGF) and chemokines/cytokines to determine the potential role of urine biomarkers as patient selection and surrogate endpoints of treatment outcome predictors. Now: At baseline and each follow-up period, urine will be collected for analysis of biomarkers for nerve growth factor (NGF) and chemokines/cytokines to determine the potential role of urine biomarkers as patient selection and surrogate endpoints of treatment outcome predictors. Clarification of detrusor overactivity: Eligibility – Inclusion #7, page 17 Was: Volunteer has detrusor overactivity (defined as a phasic rise in bladder pressure during the filling phase determined by urodynamics) demonstrated during the screening period or Day 1 (prior to randomization, or if within 3 months of screening if patient is off antimuscarinic/anticholinergic drugs at the time of urodynamic testing). Now: Volunteer has detrusor overactivity (defined as a phasic rise in bladder pressure during the filling phase determined by urodynamics) demonstrated during the screening period or within 6 months of screening if patient is off antimuscarinic/ anticholinergic drugs at the time of urodynamic testing). Recruitment Process, page 19 Advertising brochures will be placed in the Urology Clinic; included in the MEDVAMC newsletter; and included in a mail out planned for potential subjects. An advertisement will be placed on the Craig's List website. Study Procedures 10.1 Screening - Visit 1, page 19 Was: Urodynamic studies: Now: Urodynamic studies (if not performed 6 months prior to the Randomization Visit): 10.3 Post Randomization/Treatment Visits (Follow Up), page 23 Was: Post Randomization/Treatment Visits (Follow Up) (Day 3 (± 3 days) weeks, and 6, 9, 12, 18, 24, and 26 months post randomization/treatment) Now: Post Randomization/Treatment Visits (Follow Up) -Day 3, and Weeks 4, 12, and 24 (± 3 days) post randomization/treatment 10.3.2 Visit 4, page 23 Was: Visits 4, 5, and 7: Weeks 4, 8, and 16 (± 3 days) post randomization/treatment Now: Week 4 (± 3 days) post randomization/treatment 10.3.3. Visit 5, page 23 Was: Visit 6: Week 12 (± 3 days) post randomization/treatment Now: Visit 5: Week 12 (± 3 days) post randomization/treatment 10.3.4. Visit 8 Week 20 (± 3 days) post randomization/treatment, page 23 Deleted study visit 10.3.5. End of Study Visit, page 23 Was: Visit 10: Week 26 (± 3 days) post Visit 9 - End of Study Visit Now: Visit 6: Week 24 (± 3 days) post randomization/treatment - End of Study Visit Was: Urodynamic studies no longer required at End of Study Visit

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Amendment Submit Date: 05/29/2013
Reason: Multiple Amendments
Description: Protocol v.4/30/13 changes: 1. Clarification of time frame for washout period for antimuscarinic/anticholinergic drugs: Eligibility – Inclusion #7, page 17 Was: Volunteer has detrusor overactivity (defined as a phasic rise in bladder pressure during the filling phase determined by urodynamics) demonstrated during the screening period or Day 1 (prior to randomization). Now: Volunteer has detrusor overactivity (defined as a phasic rise in bladder pressure during the filling phase determined by urodynamics) demonstrated during the screening period or Day 1 (prior to randomization, or if within 3 months of screening if patient is off antimuscarinic/anticholinergic drugs at the time of urodynamic testing). Eligibility – Exclusion #2, page 18 Was: Volunteer has had previous or current botulinum toxin therapy of any serotype for any urological condition or, treatment within 6 months of Randomization/Day 1 for any other condition or use Now: Volunteer has had previous or current botulinum toxin therapy of any serotype for any urological condition within 9 months or, treatment within 3 months of Randomization/Day 1 for any other condition or use. 2. Bladder ultrasound no longer required: 10.1, page 19; 10.3.4, page 23; and 10.3.6, page 24 Was: Bladder and Kidney ultrasounds Now: Kidney ultrasound or results of exam conducted within 6 months of Visit 1. The HPR and ICD have been revised to reflect these changes.

Amendment Submit Date: 05/29/2013
Reason: Multiple Amendments
Description: Protocol v.4/30/13 changes: 1. Clarification of time frame for washout period for antimuscarinic/anticholinergic drugs: Eligibility – Inclusion #7, page 17 Was: Volunteer has detrusor overactivity (defined as a phasic rise in bladder pressure during the filling phase determined by urodynamics) demonstrated during the screening period or Day 1 (prior to randomization). Now: Volunteer has detrusor overactivity (defined as a phasic rise in bladder pressure during the filling phase determined by urodynamics) demonstrated during the screening period or Day 1 (prior to randomization, or if within 3 months of screening if patient is off antimuscarinic/anticholinergic drugs at the time of urodynamic testing). Eligibility – Exclusion #2, page 18 Was: Volunteer has had previous or current botulinum toxin therapy of any serotype for any urological condition or, treatment within 6 months of Randomization/Day 1 for any other condition or use Now: Volunteer has had previous or current botulinum toxin therapy of any serotype for any urological condition within 9 months or, treatment within 3 months of Randomization/Day 1 for any other condition or use. 2. Bladder ultrasound no longer required: 10.1, page 19; 10.3.4, page 23; and 10.3.6, page 24 Was: Bladder and Kidney ultrasounds Now: Kidney ultrasound or results of exam conducted within 6 months of Visit 1. The HPR and ICD have been revised to reflect these changes.

Amendment Submit Date: 01/31/2013
Reason: Other Amendment
Description: This protocol is being funded by the DOD. For research determined to be greater than minimal risk, DODI 3216.02 requires that the IRB approve, by name, an independent research monitor with expertise consonant with the

nature of risk(s) identified within the research protocol. The IRB must approve a written summary of the monitors' duties, authorities, and responsibilities. The research monitor's duties should be based on specific risks or concerns about the research. The research monitor may perform oversight functions and report their observations and findings to the IRB or a designated official. The research monitor may be identified from within or outside the PI's institution. Donald P. Griffith, MD, Chief of the Urology Service at MEDVAMC, is the research monitor for this study. As part of his function as Chief, he has participated in many clinical research studies and is aware of the concerns for the protection of human research subjects. He has knowledge of the mechanisms of the two study agents (onabotulinumtoxinA and oxybutynin). His research monitor functions may include: • observing recruitment and enrollment procedures and the consent process, • discussing with the investigators with regards to the protocol's study interventions and interactions, • reviewing monitoring plans and UPIRTSO reports; • reviewing data matching, data collection, and analysis In addition, Dr. Griffith shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor's report. He shall also have the responsibility to promptly report their observations and findings to the IRB or other designated official and the HRPO. Dr. Griffith's CV and CITI MEDVAMC human subject's protection training documentation is attached in Section S.

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Amendment Submit Date: 06/19/2012
Reason: Other Amendment
Description: The VA Biomedical Laboratory Research and Development Service has requested the following changes: In the consent form: - Please indicate if the specimens will be shared with other researchers for other approved research protocols. - Please disclose any potential commerical benefits and if the subject will receive additional money or other benefits from future testing on their specimens. - Please indicate that no genetic testing will be performed

on specimens. - Clarify coding system. Changes to the HPR: - Clarify coding system of specimens sent to Dr. Chancellor. All requested changes have been completed.

April 10, 2014

CHRISTOPHER PATRICK SMITH
BAYLOR COLLEGE OF MEDICINE
UROLOGY

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Phone: (713) 798-6970
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Email: irb@bcm.tmc.edu

H-26296 - A DOUBLE-BLIND, RANDOMIZED STUDY OF THE SAFETY AND EFFICACY OF ONABOTULINUMTOXINA (ONABONT-A) VERSUS ORAL OXYBUTYNIN IN SPINAL CORD INJURED PATIENTS WITH NEUROGENIC DETRUSOR OVERACTIVITY (PROTOCOL NUMBER 11-09-10-04)

APPROVAL VALID FROM 4/10/2014 TO 3/11/2015

Dear Dr. SMITH

The Institutional Review Board for Human Subject Research for Baylor College of Medicine and Affiliated Hospitals (BCM IRB) is pleased to inform you that the research protocol and consent form(s) named above were approved.

The study may not continue after the approval period without additional IRB review and approval for continuation. You will receive an email renewal reminder notice prior to study expiration; however, it is your responsibility to assure that this study is not conducted beyond the expiration date.

Please be aware that only IRB-approved informed consent forms may be used when written informed consent is required.

Any changes in study or informed consent procedure must receive review and approval prior to implementation unless the change is necessary for the safety of subjects. In addition, you must inform the IRB of adverse events encountered during the study or of any new and significant information that may impact a research participants' safety or willingness to continue in your study.

The BCM IRB is organized, operates, and is registered with the United States Office for Human Research Protections according to the regulations codified in the United States Code of Federal Regulations at 45 CFR 46 and 21 CFR 56. The BCM IRB operates under the BCM Federal Wide Assurance No. 00000286, as well as those of hospitals and institutions affiliated with the College.

Sincerely yours,

RAYAN KAMAL AL JURDI, M.D., B.S.
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Subject Name: _____ **Date:** _____

Subject Initials: _____

Principal Investigator: CHRISTOPHER PATRICK SMITH **VAMC:** _____

H-26296 - A DOUBLE-BLIND, RANDOMIZED STUDY OF THE SAFETY AND EFFICACY OF ONABOTULINUMTOXINA (ONABONT-A) VERSUS ORAL OXYBUTYNIN IN SPINAL CORD INJURED PATIENTS WITH NEUROGENIC DETRUSOR OVERACTIVITY (PROTOCOL NUMBER 11-09-10-04)

OnaBoNT-A versus Oxybutynin ER in Patients (Veterans) with SCI and NDO

Background

Please read this form carefully. Take time to ask the doctor or study staff as many questions about the study as you would like. If there are any words or information that you do not understand, the doctor or study staff will explain them to you. Reading this form and talking to the doctor or study staff may help you decide whether to participate or not. If you decide to take part in the study, you must sign and date the statement of consent and authorization on the last page of this form.

Neurogenic detrusor overactivity (NDO) is a condition in which the bladder is hyperactive, often resulting in urinary incontinence (UI - not able to control urine flow). A patient who has a spinal cord injury (SCI) often suffers with NDO.

Current treatment of UI resulting from NDO includes drugs that may help with the incontinence but they are likely to cause dry mouth, constipation and blurred vision.

OnaBoNT-A [BOTOX (R)] bladder injections have been studied in other clinical research trials in patients who have not responded to oral medications. The results have shown an improvement in how often urine leakage happens and an increase in the amount of urine the bladder can hold. OnaBoNT-A is approved by the FDA for bladder injections.

Oxybutynin ER (extended release) relaxes bladder smooth muscle. In patients with UI, studies have demonstrated that Oxybutynin ER increases bladder capacity, diminishes the frequency of urine loss, and delays the initial desire to urinate. Oxybutynin ER thus decreases urgency and the frequency of both incontinent episodes and voluntary urination. Oxybutynin ER is approved by the FDA for patients with UI.

You are being asked to participate in this clinical research study because you are a veteran with a spinal cord injury and have NDO.

This study is funded by the sponsor, the Department of Defense.

Purpose

This purpose of this clinical trial is to see if onaBoNT-A is safe and how well it works when injected into the bladder for the treatment of UI and if it works better than oxybutynin [Ditropan (R)] that is taken by mouth. A second purpose of the study is to perform research tests on your urine samples. Urine presents a rich source of information for bladder diseases and the biomarkers (the chemical

make-up of the urine cells) will be examined to learn if there are yet undiscovered reasons for urinary diseases.

OPTIONAL RESEARCH: Future research projects using your urine samples may lead to better treatment of urinary diseases.

Procedures

The research will be conducted at the following location(s): Baylor College of Medicine, Michael E. DeBakey Veterans Affairs Medical Center.

If you decide to be in this study, you will be asked to sign this informed consent document. You will be taking part in the study for at least 6-7 months and will visit the clinic at least 5 times.

This is a double blind study, which means that neither you nor your study doctor will know which study drugs you are receiving. However, your study doctor can get this information quickly in case of a health-related emergency.

You will be randomized to one of two treatments. The treatment you will be receiving is determined by random like the toss of a coin. You will have a 50-50 chance of receiving either treatment. The treatments are ARM 1: onaBoNT bladder injection and a placebo (sugar pill) oral medication once a day; or ARM 2: placebo (saline or salt water) bladder injection and Oxybutynin ER (like Ditropan) capsule once a day.

VISIT 1 - Screening

After your informed consent is obtained, the following will occur at least 2 weeks but not more than 4 weeks prior to Visit 2: randomization and bladder injection:

1. You will have a physical examination. The study staff will ask about your medical history including the medications you are now taking and procedures you have had.
2. Your vital signs (blood pressure, temperature and pulse rate) and weight will be measured.
3. You will have a kidney ultrasound or results of exam conducted within 6 months of Visit 1. An ultrasound test is a radiology technique, which uses high -frequency sound waves to produce images of the organs and structures of the body. The sound waves are sent through body tissues with a device called a transducer. The transducer is placed directly on top of the skin, which has a gel applied to the surface. The sound waves that are sent by the transducer through the body are then reflected by internal structures as "echoes." These echoes return to the transducer and are transmitted electrically onto a viewing monitor. After the ultrasound, the gel is easily wiped off.

4. You will give about 3 teaspoons of blood to test the following:
- To see if your blood count is normal.
- If you are a female, to confirm that you are not pregnant.
- If you are a male, to test your PSA (Prostate specific antigen) which is a test used to screen for cancer of the prostate.

5. You will give a urine sample for routine tests and to use as a baseline for research testing.

6. You will have urodynamic studies to give a baseline reading of what your bladder function is before you start the treatment. If you have had these studies within the past six months and you were not taking an medications for your overactive bladder, you will not need the studies at this visit. This test gives the doctors detailed information about the way your bladder and bladder outlet (the urethra) work when you try to urinate. It helps explain why you may have difficulty holding urine or urinary frequency. During this procedure, catheters with pressure sensors are placed through the urethra into your bladder and also into your rectum. The pressure in your bladder and rectum are measured while your bladder is filled with saline or dye solution. You will be asked questions about how full you feel and when you have the urge to urinate. You will be asked to urinate, if possible, during the study. X-rays and photos may be taken during the study.

7. If you are able to urinate, you will have a PVR (Post-Void Residual) test. The volume of fluid remaining in the bladder immediately after you urinate will be measured by catheterization (tube inserted into your bladder), or abdominal or vaginal ultrasound.

8. You will be given a bladder diary to keep track of the number of times you urinate, the amount, any leakage, etc. for 7 straight days in the week prior to next clinic visit.

9. You will be given a prescription for an antibiotic. You will take the antibiotic 3 days BEFORE your next visit, on the morning of the visit, and for 3 days AFTER the bladder injection.

VISIT 2: Randomization and Treatment (14 days to 6 weeks after Visit 1)

The following procedures and events will happen during this visit.

1. Your vital signs and weight will be measured.
2. If you are a female, your give about 2 teaspoons of blood to confirm that you are not pregnant.
3. You will give a urine sample for routine tests and to use as a baseline for research testing.
4. If you are able to urinate, you will have a PVR.
5. The study doctor or a study staff member will review your current medications and ask about any problems you may have had since the last study visit.
6. You will complete the Incontinence Quality of Life questionnaire (I-QOL) and Incontinence Quality of Life neurogenic module (I-QOLNM) questionnaires prior to treatment. It will take about 15-20 minutes to complete the questionnaires.
7. Your bladder diary will be reviewed by the study staff. You will be given a bladder diary to keep

track of the number of times you urinate, the amount, any leakage, etc. for 7 straight days in the week prior to next clinic visit.

You will be randomized into your treatment group.

After randomization, the following events will occur:

8. Your bladder injection procedure will be done according to standard procedures in the clinic. The doctor wll decide if you will be given a local anesthesia to lessen the pain before beginning the injection procedure. Your bladder will be filled with saline so that the area is free of urine. The injection will be given. The study doctor will discuss the procedure with you. After the injection, you will be observed for at least 30 minutes before you can go home. You will be instructed to continue your antibiotics for 3 more days.
9. You will be given the study oral medication dose while at the clinic and some to take home. You are to take the study medication once a day every day. You will be given a diary that you will complete to help you remember to take your medication. Please bring the pill bottle and the diary with you to your next clinic visit.
10. You will complete the bladder diary for 7 consecutive days in a row prior to next clinic visit in about 2 weeks.

VISIT 3: Telephone Visit (Day 3 to 5 after injection)

You will be contacted by telephone to discuss your well-being, any changes in your medications, your antibiotic compliance, and any side-effects or adverse events you may have experienced.

VISITS 4: Week 4 after injection (plus or minus 3 days)

1. Your vital signs and weight will be measured.
2. If you are able to urinate, you will have a PVR test.
3. If you are a female, your give about 2 teaspoons of blood to confirm that you are not pregnant.
4. You will give a urine sample for routine tests and research testing.
5. Your bladder diary will be reviewed by the study staff. You will be given a bladder diary to keep track of the number of times you urinate, the amount, any leakage, etc. for 7 straight days in the week prior to next clinic visit.
6. The study doctor or a study staff member will review your medications and ask about any adverse events you may have had.
7. You will complete the I-QOL, I-QOLNM, OAB-Patient Satisfaction with Treatment Questionnaire (OAB_PSTQ), and Patient Global Assessment (PGA) questionnaires. It will take you about 20 to 30

minutes to complete them.
8. You will be given the study oral medication dose and the pill diary. Please bring the pill bottle and the diary with you to your next clinic visit.

VISIT 5: Week 12 after injection (plus or minus 3 days)

The procedures for this clinic visit are the same as VISIT 4. In addition, you will also undergo a urodynamic study.

VISIT 6: Week 24: End of Study/Study Exit (2 weeks plus or minus 3 days after injection)

1. You will undergo a physical examination that includes your vital signs and weight measurements.
2. If you are able to urinate, you will have a PVR test.
3. You will give a urine sample for routine tests and research testing.
4. You will give about 3 teaspoons of blood to check your general health.
5. If you are a female, your give about 2 teaspoons of blood to confirm that you are not pregnant.
6. You will have a kidney ultrasound.
7. You will give your completed bladder diary to the study doctor or staff.
8. The study doctor or a study staff member will review your medications and ask about any adverse events you may have had.
9. You will complete same 4 questionnaires as you did in VISIT 4.

This ends your participation in this research study.

If you are a male, you will have a total of approximately 6 teaspoons of blood drawn during the study. If you are a female, you will have a total of approximately 12 teaspoons of blood drawn during the study.

A portion of your urine samples will be sent to the Beaumont Research Institute at the Oakland University William Beaumont School of Medicine in Royal Oak, MI for research testing conducted under the supervision of Dr. Michael B. Chancellor. The samples will be coded so that only your study doctor will know how to link your name and other identifying information with the coded sample. The staff at the testing site will not be able to link the code to your information.

OPTIONAL RESEARCH:

With your permission, after research testing required for this study is completed, the remaining portion of your samples will be stripped of the code and will be banked for future use. It will be kept until it is

all gone. Your samples will not be sold or transferred to anyone else but may be shared with the study doctor's colleagues for approved research studies. If at any time you withdraw from this study, you will not be able to get your urine samples back. You can't request that they be destroyed because the samples can't be linked to you.

Genetic testing will not be conducted on your specimens.

This institution does not plan to pay royalties to you if a commercial product is developed from blood or tissue obtained from you during this study.

You can participate in this study if you choose not to have your samples banked..

Please see next to last page of this consent form to choose your choice for this optional research.

Your research doctor may never be able to provide you with your research related health information.

Potential Risks and Discomforts

OnaBoNT-A: It is expected that you may have some or all of the following side effects when given onaBoNT-A. Other side effects may occur which were not seen before. Side effects are usually temporary and manageable. However, it is possible they could cause serious disease or death. The study may include risks that are unknown at this time.

There have been rare reports of serious and/or immediate or even deadly abnormally sensitive reactions after treatment with onaBoNT-A. These reactions include allergic reaction, skin rash, itching, swelling, and difficulty in breathing.

It is a rare possibility that the injection of onaBoNT-A could lead to botulism. The classic symptoms of botulism include double vision, blurred vision, drooping eyelids, slurred speech, difficulty swallowing, dry mouth, and muscle weakness. The doctor's examination may reveal that the gag reflex and the deep tendon reflexes like the knee jerk are decreased or absent.

There have been rare reports of sudden death, sometimes associated with difficulty in swallowing or pneumonia. There have also been rare reports of heart problems (including irregular heart beats and heart attack, some resulting in death). Some of these patients already had or were at risk for heart disease. It is not known if onaBoNT-A actually caused these problems.

It should not be used when infection is present at the injection site or if you are known to be abnormally sensitive to onaBoNT-A.

Subject Name: _____ **Date:** _____

Subject Initials: _____

Principal Investigator: CHRISTOPHER PATRICK SMITH **VAMC:** _____

H-26296 - A DOUBLE-BLIND, RANDOMIZED STUDY OF THE SAFETY AND EFFICACY OF ONABOTULINUMTOXINA (ONABONT-A) VERSUS ORAL OXYBUTYNIN IN SPINAL CORD INJURED PATIENTS WITH NEUROGENIC DETRUSOR OVERACTIVITY (PROTOCOL NUMBER 11-09-10-04)

The following events have been observed since onaBoNT-A has been marketed: skin rash, itching, and allergic reaction. In general, these side effects occur within the first week following injection and, while usually temporary, they may last several months. Pain, tenderness, or bruising around the injection site may also occur. Local weakness of the injected muscle(s) is expected. Weakness of nearby muscles may also occur due to spread of onaBoNT-A.

OnaBoNT-A contains albumin, which comes from human blood. Although the blood is rigorously tested, there is an extremely remote risk for the transmission of viruses and similar infectious agents.

OXYBUTYNIN ER: Common Side Effects: Blurred vision; constipation; diarrhea; dizziness; drowsiness; dry eyes, nose, skin, or mouth; headache; indigestion; nausea; runny nose; stomach pain or upset; trouble sleeping; weakness

Severe Side Effects: Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); confusion; difficult or painful urination; fast or irregular heartbeat; fever; hallucinations; mental or mood changes (e.g., agitation); seizures; swelling of the hands, ankles, or feet; vision problems.

Oxybutynin ER is contraindicated in patients with urinary retention, gastric retention and other severe decreased gastrointestinal motility conditions, uncontrolled narrow-angle glaucoma and in patients who are at risk for these conditions.

Oxybutynin ER is also contraindicated in patients who have demonstrated hypersensitivity to the drug substance or other components of the product.

The concomitant use of Oxybutynin ER with other anticholinergic drugs (used to relieve cramps or spasms of the stomach, intestines, and bladder) or with other agents that produce dry mouth, constipation, somnolence (drowsiness), and/or other anticholinergic-like effects may increase the frequency and/or severity of such effects.

The safety of Oxybutynin ER administered to women who are or who may become pregnant or are breastfeeding has not been established. Therefore, Oxybutynin chloride should not be given to pregnant women unless, in the judgment of the physician, the probable clinical benefits outweigh the possible hazards.

LIDOCAINE® (given to deaden the area around the injection site): The amount of Lidocaine that you will receive usually does not cause any side effects.

Rarely, the following side effects may be experienced:

- lightheadedness
- nervousness
- anxious or scared
- feeling of well being and great happiness
- confusion
- dizziness
- drowsiness
- ringing or buzzing in the ear
- blurred or double vision
- vomiting
- sensations of heat, cold or numbness
- slight jerking motions
- shaking
- convulsions or seizures
- loss of awareness of surroundings
- difficulty breathing or not breathing at all
- slow heart beat
- low blood pressure
- stopping of the heart

Extremely rare side effects include hives, swelling, and shock.

PLACEBO: Since placebo has no active drug, your overactive bladder condition may become worse, stay the same or improve.

ANTIBIOTICS: An antibiotic may cause upset stomach, diarrhea, vomiting, skin rash, itching, hives, difficulty breathing or swallowing, wheezing, unusual bleeding or bruising, sore throat, painful mouth or throat sores, and vaginal infection. Please read the package insert that will be provided for additional information.

CYSTOSCOPY WITH BLADDER INJECTION: The discomfort is nearly identical to being catheterized, which generally causes slight to moderate discomfort. There will be a feeling of fullness in the bladder and a sensation to empty during the cystoscopy examination. Bleeding, infection, damage to urethra or surrounding structures may occur.

Subject Name: _____ **Date:** _____

Subject Initials: _____

Principal Investigator: CHRISTOPHER PATRICK SMITH **VAMC:** _____

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PVR: The risks of having a catheter placed in the bladder for draining the residual urine are infection of the urinary tract, injury to the urethra caused by rough insertion of the catheter, narrowing of the urethra due to scar tissue caused by the insertion of a catheter, injury to the bladder caused by incorrect insertion of the catheter.

URODYNAMICS: Generally the risks of an urodynamic study are low and are no more than those of a Foley Catheter insertion, which include the possibility of infection, trauma to the urethra or prostate, traumatic bleeding from the catheterization, discovery of previously unsuspected urethral stricture with inability to get the urodynamics catheter into the bladder.

Patients with a spinal cord injury generally occurring at the Thoracic 5 (T-5) level and above have a risk of experiencing autonomic dysreflexia during bladder filling during the urodynamic or study treatment procedures. Autonomic dysreflexia can develop suddenly, and is a possible emergency situation. Symptoms of autonomic dysreflexia include the following: elevation in blood pressure, headache, goose pimples, sweating above the level of injury, nasal congestion, slow pulse, blotching of the skin, and restlessness. If not treated promptly and correctly, it may lead to seizures, stroke, and in some cases, even death. To minimize this risk continuous blood pressure monitoring is performed throughout the study.

ULTRASOUND: Ultrasound testing is painless and harmless but the volunteer might experience anxiety in anticipation of the test. Ultrasound tests involve no radiation and studies have not revealed any adverse effects.

BLOOD DRAWS: Inserting needles into veins for collecting blood may be uncomfortable. Risks include slight bruising at the puncture site, fainting, the formation of a small blood clot or swelling of the vein and surrounding tissue, bleeding from the site, and the remote possibility of infection at the site of the needle puncture. Fainting is usually harmless, of short duration, and typically produces feelings of weakness, sweating, slowing of the heart rate and an abnormal decrease in blood pressure. Care will be taken to avoid these complications.

QUESTIONNAIRES: Completing the questionnaires may cause you to have or to experience some level of emotional discomfort due to the personal nature of the questions. The study doctor and staff will maintain a professional and caring attitude while administering the questionnaires.

LOSS OF CONFIENTIALITY: The loss regarding research information is a possibility, although, the risk is extremely small. The investigator and his staff will make every effort to maintain the confidentiality. Your urine specimens will labeled with your subject code before being sent to Dr. Chancellor's laboratory. The laboratory personnel will not be able to know that these specimens are

yours. Study documents kept at Michael E. DeBakey Veterans Affairs Medical Center (MEDVAMC) may include your initials and subject code but no other identifying information. Any of your information or specimens will not contain your initials if they leave MEDVAMC.

PREGNANCY: It is possible that the medicines used in this study could injure a fetus if volunteer or volunteer's partner becomes pregnant while taking them. Pregnant and/or lactating women will be excluded from the study. Because of the potential risks involved, pregnancy should not occur during participation in this study. The following methods of contraception, if properly used, are generally considered reliable for females of childbearing potential who may participate in the study: oral contraceptives, patch contraceptives, injection contraceptives, male condom with intravaginal spermicide, diaphragm or cervical cap with spermicide, vaginal contraceptive ring, intrauterine device, surgical sterilization (bilateral tubal ligation), vasectomized partner(s), or total sexual abstinence. Both males and females should use birth control.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study.

Potential Benefits

The benefits of participating in this study may be: improvement in urinary incontinence symptoms, decrease in the occurrence of urinary tract infections, decrease in the number of required catheterizations, and an ease of the financial burden of buying protective garments. However, you may receive no benefit from participating.

Alternatives

The following alternative procedures or treatments are available if you choose not to participate in this study: oral medications or invasive surgery to enlarge your bladder with intestine.

Subject Costs and Payments

Standard of Care: Services provided at the MEDVAMC for this disease state include clinic visits, PVRs, Kidney ultrasounds (Visits 1 and End of Study), urodynamics studies, PSA, and urinalyses. These services will be billed/paid as normally done through the MEDVAMC.

Research Costs: The events and procedures that will be paid by the study sponsor are the kidney ultrasound at Visit 2, the pregnancy tests at Visits 1, 2, 4, 5, and 6 and all study medications.

Subject Name: _____ **Date:** _____

Subject Initials: _____

Principal Investigator: CHRISTOPHER PATRICK SMITH **VAMC:** _____

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You will receive $50 for completing each of the study visits 2, 4, 5, and 6 for a total of $200 if all visits are completed. In order for you to receive the stipend, you will provide your name, address, telephone number, and Social Security number. You will complete the BCM Research Participant/Donor Compensation form. A check will be mailed to you.

Research Related Injury

If you experience a research related injury, please contact the Dr. Smith immediately at 713-798-4001. He will instruct you on what procedures to follow in order to receive treatment for the injury.

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Women of Childbearing Potential

It is possible that the medicines used in this study could injure a fetus if you or your partner becomes pregnant while taking them. Because of the potential risks involved, you or your partner should not become pregnant while you are participating in this study.

If you are sexually active or become sexually active and can get pregnant or can get your partner pregnant, you must agree to use one of the following forms of birth control every time you have sex:

* oral contraceptives ("the pill"),
* intrauterine devices (IUDs),
* contraceptive implants under the skin, or contraceptive injections,
* condoms with foam.

Should you become pregnant while on this study, you must immediately notify the study personnel.

The investigator will assist you in finding appropriate medical care. The investigator also may ask to be allowed to continue getting information about your pregnancy. You can choose not to provide this information.

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time.

Subject Name: _____ **Date:** _____

Subject Initials: _____

Principal Investigator: CHRISTOPHER PATRICK SMITH **VAMC:** _____

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Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

Your Health Information

Your signature on this form means that you give permission for the use and disclosure of your protected health information for this research study. Federal law requires that the Michael E. Debakey Veterans Affairs Medical Center protect health information linked to your identity. The procedures section above provides the specific information and the person(s) who would use or disclose it.

If you decide not to give your permission for the use and disclosure of your protected health information as we have described for this study, you will receive access to the same treatment, payment, enrollment or eligibility for benefits as you normally would.

People who give medical care and ensure quality from the institutions where the research is being done, the sponsor(s) listed in the sections above, representatives of the sponsor, and regulatory agencies such as the U.S. Department of Health and Human Services will be allowed to look at sections of your medical and research records related to this study. Because of the need for the investigator and study staff to release information to these parties, complete privacy cannot be guaranteed.

If you decide to take part in the study, your protected health information will not be given out except as allowed by the regulations or as described in this form. The results of the data from the study may be published. However, you will not be identified by name. People who receive your protected health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them.

You may decide that you no longer allow protected health information that identifies you to be used or disclosed for this research study. Contact the study staff to tell them of this decision, and they will give you an address so that you can inform the investigator in writing. The investigator will honor this decision unless the researchers have already acted in reliance on your information. Then it will not be possible to honor your decision in this way.

The people listed above will be able to access your information for as long as they need to, even after the study is completed.

Subject Name: _____ **Date:** _____

Subject Initials: _____

Principal Investigator: CHRISTOPHER PATRICK SMITH **VAMC:** _____

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The investigator, CHRISTOPHER PATRICK SMITH, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: CHRISTOPHER PATRICK SMITH at 713-798-4001 24 hours a day.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

Under Federal Regulations, the VA Medical facility shall provide necessary medical treatment to you as a research subject injured as a result by participation in a research project approved by a VA Research and Development Committee and conducted under the supervision of one or more VA employees. This requirement does not apply to treatment for injuries that result from non-compliance by a research subject with study procedures. If you sustain an injury as a direct result of your study participation, medical care will be provided by the Michael E. DeBakey VA Medical Center. The Department of Veterans Affairs does not normally provide any other form of compensation for injury. You do not waive any liability rights for personal injury by signing this form.

You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled. Your participation will not affect the way you now pay for medical care at the VAMC. If you would like to verify the validity of the study and authorized contacts, you may speak with the Michael E. DeBakey Veterans Affairs Medical Center Research Office at 713-794-7918 or 713-794-7566.

SAMPLE STORAGE: You are being asked to agree to allow samples of your urine samples which will be stored as described in the Procedures section of this informed consent document, to be used for current research use. You are also being asked to agree to allow the use of stored materials for future research use. Complete confidentiality will be maintained and these samples will not be tracked back to you, except by using records available only to the Principal Investigators, the Co-Investigators, and your urologist.

PLEASE CIRCLE YOUR CHOICES AND INITIAL:

Samples used for current research: ____YES ____NO _____INITIALS

Subject Name: _____ **Date:** _____

Subject Initials: _____

Principal Investigator: CHRISTOPHER PATRICK SMITH **VAMC:** _____

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Samples used for future research: ____YES ____NO _____INITIALS

Department of Veterans Affairs

VA RESEARCH CONSENT FORM

HIPAA Compliant

Subject Name: _____ **Date:** _____

Subject Initials: _____

Principal Investigator: CHRISTOPHER PATRICK SMITH **VAMC:** _____

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

_____ _____

Subject Date

_____ _____

Investigator or Designee Obtaining Consent Date

_____ _____

Witness Date

Incontinence Quality of Life Instrument Neurogenic Module

PLEASE READ THIS CARFEULLY

PLEASE CHOOSE THE RESPONSE THAT APPLIES BEST TO YOU RIGHT NOW AND CIRCLE THE NUMBER OF YOUR ANSWER.

IF YOU ARE UNSURE ABOUT HOW TO ANSWER A QUESTION, PLEASE GIVE THE BEST ANSWER YOU CAN.

THERE ARE NO RIGHT OR WRONG ANSWERS.

YOUR ANSWERS WILL BE KEPT STRICTLY

Incontinence Quality Of Life Neurogenic Module

(Please circle the number of your answer.)

1. I have to limit caffeine drinks or alcohol because of my urinary problems or incontinence.

    1. EXTREMELY
    2. QUITE A BIT
    3. MODERATELY
    4. A LITTLE
    5. NOT AT ALL

2. I worry about the long-term effect of catheterizations on my urinary tract infections or other health problems.

    1. EXTREMELY
    2. QUITE A BIT
    3. MODERATELY
    4. A LITTLE
    5. NOT AT ALL

3. Accessibility and privacy in public toilets are important to me.

    1. EXTREMELY
    2. QUITE A BIT
    3. MODERATELY
    4. A LITTLE
    5. NOT AT ALL

Continued on next page

(Please circle the number of your answer.)

4. It bothers me to have to catheterize on a regular schedule.

    1. EXTREMELY
    2. QUITE A BIT
    3. MODERATELY
    4. A LITTLE
    5. NOT AT ALL

5. It bothers me to have to use incontinence pads or diapers.

    1. EXTREMELY
    2. QUITE A BIT
    3. MODERATELY
    4. A LITTLE
    5. NOT AT ALL

END OF QUESTIONNAIRE

THANK YOU FOR YOUR RESPONSES

INCONTINENCE QUALITY OF LIFE INSTRUMENT (I-QOL)

PLEASE READ THIS CARFEULLY

ON THE FOLLOWING PAGES YOU WILL FIND SOME STATEMENTS THAT HAVE BEEN MADE BY PEOPLE WHO HAVE URINARY INCONTINENCT (LEAKING URINE WHEN YOU DON'T WANT TO).

PLEASE CHOOSE THE RESPONSE THAT APPLIES BEST TO YOU RIGHT NOW AND CIRCLE THE NUMBER OF YOUR ANSWER.

IF YOU ARE UNSURE ABOUT HOW TO ANSWER A QUESTION, PLEASE GIVE THE BEST ANSWER YOU CAN.

THERE ARE NO RIGHT OR WRONG ANSWERS.

YOUR ANSWERS WILL BE KEPT STRICTLY

Incontinence Quality Of Life

Your Feelings

(Please circle the number of your answer.)

1. I worry about not being able to get to the toilet on time.

    1. EXTREMELY
    2. QUITE A BIT
    3. MODERATELY
    4. A LITTLE
    5. NOT AT ALL

2. I worry about coughing or sneezing because of my urinary problems or incontinence.

    1. EXTREMELY
    2. QUITE A BIT
    3. MODERATELY
    4. A LITTLE
    5. NOT AT ALL

3. I have to be careful standing up after I've been sitting down because of my urinary problems or incontinence.

    1. EXTREMELY
    2. QUITE A BIT
    3. MODERATELY
    4. A LITTLE
    5. NOT AT ALL

Continued on next page

(Please circle the number of your answer.)

4. I worry about where toilets are in new places.

    1. EXTREMELY
    2. QUITE A BIT
    3. MODERATELY
    4. A LITTLE
    5. NOT AT ALL

5. I feel depressed because of my urinary problems or incontinence.

    1. EXTREMELY
    2. QUITE A BIT
    3. MODERATELY
    4. A LITTLE
    5. NOT AT ALL

6. Because of my urinary problems or incontinence, I don't feel free to leave my home for long periods of time.

    1. EXTREMELY
    2. QUITE A BIT
    3. MODERATELY
    4. A LITTLE
    5. NOT AT ALL

Continued on next page

(Please circle the number of your answer.)

7. I feel frustrated because my urinary problems or incontinence prevents me from doing what I want.

    1. EXTREMELY
    2. QUITE A BIT
    3. MODERATELY
    4. A LITTLE
    5. NOT AT ALL

8. I worry about others smelling urine on me.

    1. EXTREMELY
    2. QUITE A BIT
    3. MODERATELY
    4. A LITTLE
    5. NOT AT ALL

9. My urinary problems or incontinence is always on my mine.

    1. EXTREMELY
    2. QUITE A BIT
    3. MODERATELY
    4. A LITTLE
    5. NOT AT ALL

Continued on next page

(Please circle the number of your answer.)

10. It's important for me to make frequent trips to the toilet.

    1. EXTREMELY
    2. QUITE A BIT
    3. MODERATELY
    4. A LITTLE
    5. NOT AT ALL

11. Because of my urinary problems or incontinence, it's important to plan every detail in advance.

    1. EXTREMELY
    2. QUITE A BIT
    3. MODERATELY
    4. A LITTLE
    5. NOT AT ALL

12. I worry about my urinary problems or incontinence getting worse as I grow older.

    1. EXTREMELY
    2. QUITE A BIT
    3. MODERATELY
    4. A LITTLE
    5. NOT AT ALL

Continued on next page

(Please circle the number of your answer.)

13. I have a hard time getting a good night of sleep because of my urinary problems or incontinence.

    1. EXTREMELY
    2. QUITE A BIT
    3. MODERATELY
    4. A LITTLE
    5. NOT AT ALL

14. I worry about being embarrassed or humiliated because of my urinary problems or incontinence.

    1. EXTREMELY
    2. QUITE A BIT
    3. MODERATELY
    4. A LITTLE
    5. NOT AT ALL

15. My urinary problems or incontinence makes me feel like I'm not a healthy person.

    1. EXTREMELY
    2. QUITE A BIT
    3. MODERATELY
    4. A LITTLE
    5. NOT AT ALL

Continued on next page

(Please circle the number of your answer.)

16. My urinary problems or incontinence makes me feel helpless.

    1. EXTREMELY
    2. QUITE A BIT
    3. MODERATELY
    4. A LITTLE
    5. NOT AT ALL

17. I get less enjoyment out of life because of my urinary problems or incontinence.

    1. EXTREMELY
    2. QUITE A BIT
    3. MODERATELY
    4. A LITTLE
    5. NOT AT ALL

18. I worry about wetting myself.

    1. EXTREMELY
    2. QUITE A BIT
    3. MODERATELY
    4. A LITTLE
    5. NOT AT ALL

Continued on next page

(Please circle the number of your answer.)

19. I feel like I have no control over my bladder.

1. EXTREMELY
2. QUITE A BIT
3. MODERATELY
4. A LITTLE
5. NOT AT ALL

20. I have to watch what or how much I drink because of my urinary problems or incontinence.

1. EXTREMELY
2. QUITE A BIT
3. MODERATELY
4. A LITTLE
5. NOT AT ALL

21. My urinary problems or incontinence limit my choice of clothing.

1. EXTREMELY
2. QUITE A BIT
3. MODERATELY
4. A LITTLE
5. NOT AT ALL

Continued on next page

(Please circle the number of your answer.)

22. I worry about having sex because of my urinary problems or incontinence.

1. EXTREMELY
2. QUITE A BIT
3. MODERATELY
4. A LITTLE
5. NOT AT ALL

END OF QUESTIONNAIRE

THANK YOU FOR YOUR RESPONSES

OAB-PATIENT SATISFACTION WITH TREATMENT QUESTIONNAIRE (OAB_PSTQ)

Please answer each questions by checking the box which best describes your situation. .

Answers should come from your alone, not family, friends, or the doctor's staff.

1. In the past 4 weeks, how satisfied have you been overall with your current or recent treatment(s)

   ☐ Very Satisfied

   ☐ Somewhat Satisfied

   ☐ Neutral

   ☐ Somewhat Dissatisfied

   ☐ Very Dissatisfied

   ☐ Does not apply to me

2. In the past 4 weeks, how satisfied have you been during your treatment's effect on how frequently you have to urinate during the **day**?

   ☐ Very Satisfied

   ☐ Somewhat Satisfied

   ☐ Neutral

   ☐ Somewhat Dissatisfied

   ☐ Very Dissatisfied

   ☐ Does not apply to me

Continued on next page

(Please place a check (√) by your answer.)

3. In the past 4 weeks, how satisfied have you been during your treatment's effect on how frequently you have to urinate during the **night**?

   ☐ Very Satisfied

   ☐ Somewhat Satisfied

   ☐ Neutral

   ☐ Somewhat Dissatisfied

   ☐ Very Dissatisfied

   ☐ Does not apply to me

4. In the past 4 weeks, how satisfied have you been during your treatment's effect on how frequently you have 'wetting accidents' due to **laughing, coughing, sneezing, or physical exercise**?

   ☐ Very Satisfied

   ☐ Somewhat Satisfied

   ☐ Neutral

   ☐ Somewhat Dissatisfied

   ☐ Very Dissatisfied

   ☐ Does not apply to me

5. In the past 4 weeks, how satisfied have you been during your treatment's effect on the uncontrollable urge to urinate?

   ☐ Very Satisfied

   ☐ Somewhat Satisfied

   ☐ Neutral

   ☐ Somewhat Dissatisfied

   ☐ Very Dissatisfied

   ☐ Does not apply to me

Continued on next page

(Please place a check (√) by your answer.)

6. In the past 4 weeks, how satisfied have you been during your treatment's effect on your ability to freely engage in social, work, or leisure activities with confidence (e.g., sports, hobbies, shopping, etc.)?

   ☐ Very Satisfied

   ☐ Somewhat Satisfied

   ☐ Neutral

   ☐ Somewhat Dissatisfied

   ☐ Very Dissatisfied

   ☐ Does not apply to me

7. In the past 4 weeks, how satisfied have you been during your treatment's effect on your enjoyment of life?

   ☐ Very Satisfied

   ☐ Somewhat Satisfied

   ☐ Neutral

   ☐ Somewhat Dissatisfied

   ☐ Very Dissatisfied

   ☐ Does not apply to me

8. In the past 4 weeks, how satisfied have you been during your treatment's effect on reducing fatigue and sleep interruptions?

   ☐ Very Satisfied

   ☐ Somewhat Satisfied

   ☐ Neutral

   ☐ Somewhat Dissatisfied

   ☐ Very Dissatisfied

   ☐ Does not apply to me

Continued on next page

(Please place a check (√) by your answer.)

9. In the past 4 weeks, how satisfied have you been during your treatment's effect on your travel?

- ☐ Very Satisfied
- ☐ Somewhat Satisfied
- ☐ Neutral
- ☐ Somewhat Dissatisfied
- ☐ Very Dissatisfied
- ☐ Does not apply to me

10. In the past 4 weeks, how satisfied have you been during your treatment's effect on your relationships with loved ones?

- ☐ Very Satisfied
- ☐ Somewhat Satisfied
- ☐ Neutral
- ☐ Somewhat Dissatisfied
- ☐ Very Dissatisfied
- ☐ Does not apply to me

11. In the past 4 weeks, how satisfied have you been during your treatment's effect on your ability to engage in sexual activity?

- ☐ Very Satisfied
- ☐ Somewhat Satisfied
- ☐ Neutral
- ☐ Somewhat Dissatisfied
- ☐ Very Dissatisfied
- ☐ Does not apply to me

Continued on next page

(Please place a check (√) by your answer.)

12. In the past 4 weeks, how satisfied have you been with the amount of money you spent on treatment(s) for overactive bladder or urinary incontinence?

- ☐ Very Satisfied
- ☐ Somewhat Satisfied
- ☐ Neutral
- ☐ Somewhat Dissatisfied
- ☐ Very Dissatisfied
- ☐ Does not apply to me

13. In the past 4 weeks, how satisfied have you been during your treatment's ability to reduce your embarrassment due to your overactive bladder or urinary incontinence?

- ☐ Very Satisfied
- ☐ Somewhat Satisfied
- ☐ Neutral
- ☐ Somewhat Dissatisfied
- ☐ Very Dissatisfied
- ☐ Does not apply to me

14. In the past 4 weeks, how would you rate the side effects due to your treatment(s)?

- ☐ No Side Effects
- ☐ Mild Side Effects
- ☐ Moderate Side Effects
- ☐ Severe Side Effects

Continued on next page

Questions 15 and 16 should only be answered at the DAY 1 visit PRIOR to the administration of the study medication.

15. Please list your top 1 or 2 primary goal(s) (top 1 or 2 only) for treatment of your overactive bladder.

1. _____

2. _____

16. What are your top 1 or 2 primary expectation(s) (top 1 or 2 only) for treatment of your overactive bladder?

1. _____

2. _____

Questions 15 and 16 should only be answered at follow-up visits AFTER the study drug administration.

15. Looking back at our primary goal(s) for treatment, how would you rate how effectively the treatment helped you achieve your stated goals?

Goal 1:

☐ No Progress in Achieving this Goal

☐ Some Progress in Achieving this Goal

☐ Moderate Progress in Achieving this Goal

☐ Significant Progress in Achieving this Goal

☐ Complete Achievement of this Goal.

Continued on next page

Goal 2 (if listed at baseline):

☐ No Progress in Achieving this Goal

☐ Some Progress in Achieving this Goal

☐ Moderate Progress in Achieving this Goal

☐ Significant Progress in Achieving this Goal

☐ Complete Achievement of this Goal.

16. Looking back at our primary expectation(s) for treatment, how would you rate how effectively the treatment met your stated expectations?

Goal 1:

☐ Did not meet this Expectation

☐ Somewhat met this Expectation

☐ Moderately met this Expectation

☐ Significantly met this Expectation

☐ Exceeded this Expectation

Goal 2 (if listed at baseline):

☐ Did not meet this Expectation

☐ Somewhat met this Expectation

☐ Moderately met this Expectation

☐ Significantly met this Expectation

☐ Exceeded this Expectation

Thank you. You have completed this questionnaire

PATIENT GLOBAL ASSESSMENT (PGA)

1. Since your last clinic visit, has there been any change in your overall symptoms related to your overactive bladder problems?

Place "X" next to the statement that most accurately reflects your opinion:

_____	-7	A very great deal worse
_____	-6	A great deal worse
_____	-5	A good deal worse
_____	-4	Moderately worse
_____	-3	Somewhat worse
_____	-2	A little worse
_____	-1	Almost the same, hardly any worse at all
_____	0	No change
_____	1	Almost the same, hardly any better at all
_____	2	A little better
_____	3	Somewhat better
_____	4	Moderately better
_____	5	A good deal better
_____	6	A great deal better
_____	7	A very great deal better

Continued on next page

1. Since your last clinic visit, has there been any change in your overall quality of life related to your overactive bladder problems?

Place "X" next to the statement that most accurately reflects your opinion:

_____	-7	A very great deal worse
_____	-6	A great deal worse
_____	-5	A good deal worse
_____	-4	Moderately worse
_____	-3	Somewhat worse
_____	-2	A little worse
_____	-1	Almost the same, hardly any worse at all
_____	0	No change
_____	1	Almost the same, hardly any better at all
_____	2	A little better
_____	3	Somewhat better
_____	4	Moderately better
_____	5	A good deal better
_____	6	A great deal better
_____	7	A very great deal better

Continued on next page

3. Since your last clinic visit, has there been any change in your activity limitations related to your overactive bladder problems?

Place "X" next to the statement that most accurately reflects your opinion:

_____	-7	A very great deal worse
_____	-6	A great deal worse
_____	-5	A good deal worse
_____	-4	Moderately worse
_____	-3	Somewhat worse
_____	-2	A little worse
_____	-1	Almost the same, hardly any worse at all
_____	0	No change
_____	1	Almost the same, hardly any better at all
_____	2	A little better
_____	3	Somewhat better
_____	4	Moderately better
_____	5	A good deal better
_____	6	A great deal better
_____	7	A very great deal better

Continued on next page

4. Since your last clinic visit, has there been any change in your overall emotions related to your overactive bladder problems?

Place "X" next to the statement that most accurately reflects your opinion:

_____	-7	A very great deal worse
_____	-6	A great deal worse
_____	-5	A good deal worse
_____	-4	Moderately worse
_____	-3	Somewhat worse
_____	-2	A little worse
_____	-1	Almost the same, hardly any worse at all
_____	0	No change
_____	1	Almost the same, hardly any better at all
_____	2	A little better
_____	3	Somewhat better
_____	4	Moderately better
_____	5	A good deal better
_____	6	A great deal better
_____	7	A very great deal better

Thank you. This completes the questionnaire.

onaBoNT-A vs. Oxybutynin for Spinal Cord Injuries with Overactive Bladders

STUDY DRUG DIARY

The study drug comes as a capsule to take by mouth. It is usually taken once a day at the same time every day.

Swallow the capsule whole with the aid of liquids; do **NOT** split, chew, crush, or open them.

The capsules should be stored at approximately 77 degrees but no lower than 59 degrees or high than 86 degrees. Protect from moisture and humidity.

Do **NOT** stop taking oxybutynin without talking to your doctor or a research study team member.

Keep the capsules and all medicines out of reach of children.

You **MUST** bring the unused study drug with you at each visit.

You **MUST** complete the drug diary on the next page.

Take the study drug exactly as directed. Do not take more or less of it or take it more often than instructed by the doctor or a research study team member.

STUDY DRUG DIARY

Subject Number _____

	WEEK	DATE	TIME PILL WAS TAKEN
Example:	**1**	**05/27/12**	**6:30 AM**
		05/28/12	**6:35 AM**
		05/29/12	**6:30 AM**

1		
2		
3		
4		

RETURN DIARY, REMAINING CAPSULES, AND CAPSULE CONTAINER

STUDY DRUG DIARY
Continued

Subject Number _____

WEEK	DATE	TIME PILL WAS TAKEN
5		
6		
7		
8		
9		

RETURN DIARY, REMAINING CAPSULES, AND CAPSULE CONTAINER

STUDY DRUG DIARY
Continued

Subject Number _____

WEEK	DATE	TIME PILL WAS TAKEN
10		
11		
12		

RETURN DIARY, REMAINING CAPSULES, AND CAPSULE CONTAINER

onaBoNT-A vs. Oxybutynin for Spinal Cord Injuries with Overactive Bladders

7-DAY URINE DIARY

Volunteer ID# _____ Visit # _____

The diary is to be completed for the 7 days in a row the week before your clinic visit. Write the current date and diary day in the **DATE** row for each day.

At the time you experience an accidental leakage of urine, rate the episode as follows in the **Leakage** column:

1 = damp or a few drops of urine
2 = wet your underwear or pad
3 = soaked underwear/clothes or emptied bladder. You may have several accidents during an hour. Please record each event.

In the **Void** column, place a check mark (√) each time you urinate in the toilet.

In the **CIC** column, please place a check each time you catheterize.

In the **Amount** column, indicate each time the number of ccs you urinated **OR** catheterized

DATE	TIME	Leakage	Void	CIC	Amount
10/1/10	12am-3:59am			√	175
	4am-4:59am				
	5am-5:59am				
	6am-6:59am			√	300
	7am-7:59am				
	8am-8:59am	1, 2			
	9am-9:59am				
	10am-10:59am				
	11am-11:59am				
	12pm-4:59pm	3, 1, 1			
	1pm-1:59pm				
	2pm-2:59pm			√	100
	3pm-3:59pm				
	4pm-4:59pm				
	5pm-5:59pm				
	6pm-6:59pm			√	200
	7pm-7:59pm				
	8pm-8:59pm	2			
	9pm-9:59pm			√	250
	10pm-10:59pm				
	11pm-11:59pm			√	150

DAY 1 of 7 DAY DIARY

Visit # _____

DATE	TIME	Leakage	Void	CIC	Amount
	12am-3:59am				
	4am-4:59am				
	5am-5:59am				
	6am-6:59am				
	7am-7:59am				
	8am-8:59am				
	9am-9:59am				
	10am-10:59am				
	11am-11:59am				
	12pm-4:59pm				
	1pm-1:59pm				
	2pm-2:59pm				
	3pm-3:59pm				
	4pm-4:59pm				
	5pm-5:59pm				
	6pm-6:59pm				
	7pm-7:59pm				
	8pm-8:59pm				
	9pm-9:59pm				
	10pm-10:59pm				
	11pm-11:59pm				

1 = Damp or a few drops of urine on underwear;

2 = Wet your underwear or pad;

3 = Soaked underwear/clothes or emptied bladder

DAY 2 of 7 DAY DIARY

Visit # _____

DATE	TIME	Leakage	Void	CIC	Amount
	12am-3:59am				
	4am-4:59am				
	5am-5:59am				
	6am-6:59am				
	7am-7:59am				
	8am-8:59am				
	9am-9:59am				
	10am-10:59am				
	11am-11:59am				
	12pm-4:59pm				
	1pm-1:59pm				
	2pm-2:59pm				
	3pm-3:59pm				
	4pm-4:59pm				
	5pm-5:59pm				
	6pm-6:59pm				
	7pm-7:59pm				
	8pm-8:59pm				
	9pm-9:59pm				
	10pm-10:59pm				
	11pm-11:59pm				

1 = Damp or a few drops of urine on underwear;

2 = Wet your underwear or pad;

3 = Soaked underwear/clothes or emptied bladder

DAY 3 of 7 DAY DIARY

Visit # _____

DATE	TIME	Leakage	Void	CIC	Amount
	12am-3:59am				
	4am-4:59am				
	5am-5:59am				
	6am-6:59am				
	7am-7:59am				
	8am-8:59am				
	9am-9:59am				
	10am-10:59am				
	11am-11:59am				
	12pm-4:59pm				
	1pm-1:59pm				
	2pm-2:59pm				
	3pm-3:59pm				
	4pm-4:59pm				
	5pm-5:59pm				
	6pm-6:59pm				
	7pm-7:59pm				
	8pm-8:59pm				
	9pm-9:59pm				
	10pm-10:59pm				
	11pm-11:59pm				

1 = Damp or a few drops of urine on underwear;

2 = Wet your underwear or pad;

3 = Soaked underwear/clothes or emptied bladder

DAY 4 of 7 DAY DIARY

Visit # _____

DATE	TIME	Leakage	Void	CIC	Amount
	12am-3:59am				
	4am-4:59am				
	5am-5:59am				
	6am-6:59am				
	7am-7:59am				
	8am-8:59am				
	9am-9:59am				
	10am-10:59am				
	11am-11:59am				
	12pm-4:59pm				
	1pm-1:59pm				
	2pm-2:59pm				
	3pm-3:59pm				
	4pm-4:59pm				
	5pm-5:59pm				
	6pm-6:59pm				
	7pm-7:59pm				
	8pm-8:59pm				
	9pm-9:59pm				
	10pm-10:59pm				
	11pm-11:59pm				

1 = Damp or a few drops of urine on underwear;

2 = Wet your underwear or pad;

3 = Soaked underwear/clothes or emptied bladder

DAY 5 of 7 DAY DIARY

Visit # _____

DATE	TIME	Leakage	Void	CIC	Amount
	12am-3:59am				
	4am-4:59am				
	5am-5:59am				
	6am-6:59am				
	7am-7:59am				
	8am-8:59am				
	9am-9:59am				
	10am-10:59am				
	11am-11:59am				
	12pm-4:59pm				
	1pm-1:59pm				
	2pm-2:59pm				
	3pm-3:59pm				
	4pm-4:59pm				
	5pm-5:59pm				
	6pm-6:59pm				
	7pm-7:59pm				
	8pm-8:59pm				
	9pm-9:59pm				
	10pm-10:59pm				
	11pm-11:59pm				

1 = Damp or a few drops of urine on underwear;

2 = Wet your underwear or pad;

3 = Soaked underwear/clothes or emptied bladder

DAY 6 of 7 DAY DIARY

Visit # _____

DATE	TIME	Leakage	Void	CIC	Amount
	12am-3:59am				
	4am-4:59am				
	5am-5:59am				
	6am-6:59am				
	7am-7:59am				
	8am-8:59am				
	9am-9:59am				
	10am-10:59am				
	11am-11:59am				
	12pm-4:59pm				
	1pm-1:59pm				
	2pm-2:59pm				
	3pm-3:59pm				
	4pm-4:59pm				
	5pm-5:59pm				
	6pm-6:59pm				
	7pm-7:59pm				
	8pm-8:59pm				
	9pm-9:59pm				
	10pm-10:59pm				
	11pm-11:59pm				

1 = Damp or a few drops of urine on underwear;

2 = Wet your underwear or pad;

3 = Soaked underwear/clothes or emptied bladder

DAY 7 of 7 DAY DIARY

Visit # _____

DATE	TIME	Leakage	Void	CIC	Amount
	12am-3:59am				
	4am-4:59am				
	5am-5:59am				
	6am-6:59am				
	7am-7:59am				
	8am-8:59am				
	9am-9:59am				
	10am-10:59am				
	11am-11:59am				
	12pm-4:59pm				
	1pm-1:59pm				
	2pm-2:59pm				
	3pm-3:59pm				
	4pm-4:59pm				
	5pm-5:59pm				
	6pm-6:59pm				
	7pm-7:59pm				
	8pm-8:59pm				
	9pm-9:59pm				
	10pm-10:59pm				
	11pm-11:59pm				

1 = Damp or a few drops of urine on underwear;

2 = Wet your underwear or pad;

3 = Soaked underwear/clothes or emptied bladder

CURRICULUM VITAE

I. GENERAL BIOGRAPHICAL INFORMATION

A. **Personal**:

1. **Name**: Christopher Patrick Smith, M.D., M.B.A., M.S.S.

Address: Academic/Research:
Michael E. DeBakey Veterans Affairs Medical
Houston, TX 77030
Clinical:
Baylor College of Medicine Medical Center
7200 Cambridge Street, 10th Floor, Suite B Houston,
TX 77030

B. **Education**:

1. **Undergraduate Education**:

08/1986-05/1990	The George Washington University Washington, DC Bachelor of Science (Zoology)

2. **Medical Education or Graduate Education:**

08/1990-06/1994	Northwestern University Medical School
01/2001-09/2002	Chicago, IL Doctor of Medicine
05/01/2011-07/27/2012	University of Pittsburgh Pittsburgh, PA Master of Business Administration
	U.S. Army War College Carlisle, PA Master of Strategic Studies

3. **Postgraduate Training**:

06/1994-07/1995 01/1996-07/1996	Intern and Resident in General Surgery Baylor College of Medicine Houston, TX
07/1995-01/1996 07/1996-06/2000	Resident in Urology Scott Department of Urology Baylor College of Medicine Houston, TX
07/2000-06/2002	NIH/K12 Physician Scientist Fellow in Neurourology and Female Urology Department of Urology University of Pittsburgh School of Medicine

C. **Academic Appointments**:

1. **Current Faculty Positions at BCM**:

08/2013-Present	Chief, SCI Urology Michael E. DeBakey Veterans Affairs Medical Center
05/2008-Present	Associate Professor of Urology Scott Department of Urology Baylor College of Medicine One Baylor Plaza Houston, TX 77030
07/2002-04/2008	Assistant Professor of Urology Scott Department of Urology Baylor College of Medicine One Baylor Plaza Houston, TX 77030

2. **Previous Faculty Position(s) at Other Institutions**:

07/2000-06/2002	Visiting Instructor Department of Urology University of Pittsburgh 3471 Fifth Avenue #700 Pittsburgh, PA 15213

3. **Current Courtesy Faculty Appointment(s) at Other Institutions**: Not Applicable

D. **Other Advanced Training Experience**:

1. **Formal Sabbatic Leave**: Not Applicable

2. **Other Specialized Training Following Academic Appointment**:

05/01/2008-12/15/2011	Career Development Award, Spinal Cord Electrophysiological Methods, Department of Veterans Affairs

E. **Other Information**:

1. **Honors or Awards**:

1990	Phi Beta Kappa
1993	Alpha Omega Alpha
05/2000	American Foundation of Urological Disease Travel Award
07/2000-06/2002	NIH/K12 Physician Scientist Fellowship in Neurourology and Female Urology
07/2000-06/2002	American Foundation of Urological Disease Scholar
02/2006	Paul Zimskind Award, Best Young Investigator, Society of Urodynamics and Female Urology
05/01/2008-12/15/2011	Career Development Award, Department of Veterans Affairs
2008	Second Prize Winner, 2008 Annual Jack Lapides Essay Contest on Urodynamics and Neurourology Research
05/01/2008-05/01/2011	Astellas/American Urological Association Foundation Rising Star in Urology Award
02/2008	Houston Top Docs 2008, *H Texas* Magazine
06/2008	Apple Award, American Spinal Injury Association (ASIA)
05/2008	Best Poster Award, American Urological Association Annual Meeting
2010	Listed in Castle Connolly's *America's Top Doctors*
05/2011	Best Poster Award, American Urological Association Annual Meeting
08/2012	Listed in U.S. News Top Doctors List, developed by *U.S. News & World Report* in collaboration with Castle Connolly Medical Ltd.
2013	Listed in Castle Connolly's *America's Top Doctors*

2. **Board Eligibility/Certification**:

02/28/2005-02/28/2025	Diplomate, American Board of Urology, #14791

Licensure:

1998	Texas	K6974
2000	Pennsylvania	MD-072219-L (Inactive)

3. **Other Nonacademic Positions**:

Military Experience:

a. **Appointments:**

1998-2001	Captain, United States Army Reserve Corps
2001-2007	Major, United States Army Reserve Corps
2007-2014	Lieutenant Colonel, United States Army Reserve Corps
2014-Present	Colonel, United States Army Reserve Corps

b. **U.S. Decorations/Badges:**

Army Commendation Medal
Army Achievement Medal
Army Reserve Components Achievement Medal
National Defense Service Medal
Armed Forces Reserve Medal with Bronze Hourglass and M-Device x 3
Global War on Terrorism Expeditionary Medal
Global War on Terrorism Service Medal
Army Service Ribbon
Army Overseas Training Ribbon
Meritorious Unit Commendation Ribbon
Army Superior Unit Award Ribbon

c. **Service:**

Source and Date of Commission: Direct Commission, August 5, 1998
Years of Active Commissioned Service: Over 1 year
Total Years of Service: Over 16 years

d. **Record of Duty Assignments:**

1999-2002	Urologist, Morrow USAR Center, Morrow, GA
2002-2003	Urologist, SGM Marcario Garcia USAR Center, Houston, TX
2003	Urologist, Landstuhl Regional Medical Center, Landstuhl, Germany (MOB for OEF)
2003-2005	Urologist, SGM Marcario Garcia USAR Center, Houston, TX
2005	Deputy Director of Urology, Womack Army Medical Center, Fort Bragg, NC (MOB for OEF)
2005-2007	Urologist, SGM Marcario Garcia USAR Center, Houston, TX

2007-2009	Branch Immaterial Officer, HQ US Army SOCOM Support Unit, Tampa, FL
2008	Senior Surveillance and Medical Operations Officer, CENTCOM AOR (MOB for OEF)
2009-Present	Urologist, Individual Ready Reserve, St. Louis, MO

II. RESEARCH INFORMATION

A. **Research Support**:

Active:

Protocol #05-09-30-03, Smith (PI) **04/2011-04/2015**
Title: H-25362: Effect of Botulinum Neurotoxin Type A Prostate Injections on Neurogenesis and Gene Profile Expression in Men With Localized Prostate Cancer and Lower Urinary Tract Symptoms/BPH. NCT01520441

Protocol # 02-10-10-05, Smith (PI) **04/01/2012-03/31/2016** **0.60 calendar**
VA Merit
Title: A Double-Blind, Randomized Study of the Efficacy of Onabotulinumtoxin-A (Onabont-A) Versus Oral Tamsulosin in Men with BPH and LUTS

Protocol 11-09-10-04, **Smith (PI)** **09/30/2012-09/29/2016** **1.2 calendar**
DOD
Title: A Double-Blind, Randomized Study of Safety and Efficacy of OnabotulinumtoxinA (OnaBoNT-A) versus Oral Oxybutynin in SCI Patients with NDO
The main purpose of this proposal that incorporates novel urine biomarker testing into existing clinical methodologies is to: 1) evaluate the efficacy of 200 U BoNT-A injected into the detrusor versus oral oxybutynin for the treatment of urinary incontinence (UI) caused by neurogenic detrusor overactivity (NDO) in spinal cord injured patients and 2) to determine the potential role of urine biomarkers in guiding the process of patient selection and identify surrogate predictors of treatment outcomes.

Previous:

DK069988, Smith (Co-I) **03/01/2005-02/28/2010** **10%**
NIH/NIDDK
Title: Nicotinic-Purinergic Modulation of Bladder Contraction
Goals: To explore mechanisms underlying changes in nicotinic-purinergic interaction that occurs in bladders after spinal cord injury or after bladder outlet obstruction.

Allergan, Inc., Smith (PI) **11/01/2005-10/31/2008** **2%**

Title: Effect of a Novel Conjugate of BTX-A Light Chain in Rat Models of Bladder Hyperactivity

NIDRR Smith (PI) **11/01/2006-10/31/2008** **5%**
Subcontract through Memorial Hermann
Title: Botulinum Toxin A Treatment of Detrusor External Sphincter Dyssynergia During Early SCI

Allergan, Inc., Smith (PI) **12/18/2006-12/17/2008** **2%**

Title: Preclinical Assessment of Botulinum Toxin (BTX-A) And Botulinum Toxin B (BTX-B) Following Bladder Injection in Rats

Foundation Award, Smith (PI) **01/01/2007-12/31/2007** **2%**
Hamill Foundation
Title: Use of Botulinum Toxin to Examine Mechanisms of Urinary Incontinence Following Radical Prostatectomy

Protocol 191622-515-00 Smith (PI) **04/01/2007-03/31/2009** **2%**
Allergan, Inc.
Title: A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study of the Safety and Efficacy of Repeat Treatment with Two Dose Levels of BOTOX (Botulinum Toxin Type A) Purified Neurotoxin Complex Followed by a Treatment with BOTOX in Patients with Urinary Incontinence Due to Neurogenic Detrusor Overactivity

DK60810 Smith (PI) **07/01/2007-06/30/2008** **2%**
NIDDK/Allergan
Title: Intraprostatic Injection of Botulinum Toxin for the Management of Benign Prostatic Hyperplasia: A Randomized Phase II Trial

Career Development Award, Smith (PI) **05/01/2008-12/15/2011** **75%**
Department of Veterans Affairs
Title: Role of Central ATP in Bladder Overactivity

Rising Star in Urology Program (PI) **05/01/2008-05/01/2011**
Astellas/AUA Foundation
Title: Role of Central ATP in Bladder Overactivity

B**.** **National Scientific Participation**:

1. **Journal Editorial Boards**: Not Applicable

2. **Review Panels**:

Reviewer, *Neurourology & Urodynamics*
Reviewer, *Journal of Urology*
Reviewer, *Urology*
Reviewer, *American Journal of Physiology*

3. **Professional Societies/Elected Positions**:

Member, American Urological Association
Member, American Association of Clinical Urologists
Member, Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction
Member, Texas Urologic Society
Member, Special Operations Medical Association
Member, South Central Section of the American Urological Association

4. **Invited Lectures, Presentations, Research Seminars**:

1. "Effect of Terazosin on Micturitional Urethral Pressure Profilometry in Men with Lower Urinary Tract Symptoms." AUA South Central Section, Bermuda, 1997.

2. "Management of Impending Penile Prosthesis Erosion with Polytetrafluoroethylene (Gore-Tex) Distal Wind Sock Graft." AUA Convention, San Diego, CA, May 1998.

3. "Urolume and Artificial Urinary Sphincter Placement in Men with Urethral Strictures and Urinary Incontinence. AUA South Central Section, Cancun, Mexico, 1998.

4. "Artificial Urinary Sphincter in Irradiated and Nonirradiated Patients Successful Outcomes." AUA South Central Section, Cancun, Mexico, 1998.

5. "Evaluation of Erectile Function in Sickle Cell Induced Priapism." AUA South Central Section, Cancun, Mexico, 1998.

6. "Neurogenic Bladder Model for Spinal Cord Injury (SCI): Transmitter Microdialysis and Chronic Urodynamics." AUA National Convention, Atlanta, GA, May 2000.

7. "Muscle Derived Stem Cells (MDC) Injected Into the Bladder Wall Can Improve Detrusor Contractility." APS, 46th Annual Conference, Las Vegas, NV, September 2000.

8. "Comparison of Autologous Muscle Derived Stem Cells (MDC) Versus Bovine Collagen Injection as Treatment of Stress Urinary Incontinence." Tissue Engineering Society, Orlando, FL, December 2000.

9. "Botulinum Toxin A: Physiologic and Clinical Effects on the Lower Urinary Tract." AUA National Convention, Anaheim, CA, June 2001.

10. "Effect of Botulinum Toxin A on Urethral Neurotransmitter release: Implications on Somatic/Autonomic Nerve Transmission." AUA National Convention, Anaheim, CA, June 2001.

11. "The Effects of Intraperitoneal Botulinum Toxin Injections on Cystometrogram (CMG), Leak Point Pressure (LPP), and Bladder Muscle Strip Contractility." AUA National Convention, Anaheim, CA, June 2001.

12. "Intravesical Capsaicin Markedly Elevates Spinal Cord Glutamate Levels: A Microdialysis Study." Neuroscience Annual Meeting, San Diego, CA, 2001.

13. **"**Botulinum Toxin A inhibits Afferent Nerve Evoked Bladder Strip Contractions." AUA National Convention, Orlando, FL, May 2002.

14. "Botulinum Toxin Urethral Sphincter Injection Restores Spontaneous Micturition in Multiple Sclerosis Women." AUA National Convention, Orlando, FL, May 2002.

15. **"**Botulinum Toxin A Inhibits Afferent Nerve Evoked Bladder Strip Contractions." International Conference 2002: Basic and Therapeutic Aspects of Botulinum and Tetanus Toxins, Hanover, Germany, May 2002.

16. "One Surgeon's Experience in 50 Patients with Botulinum Toxin Injection Into the Bladder and Urethra." International Conference 2002: Therapeutic Aspects of Botulinum and Tetanus Toxins, Hanover, Germany, June 2002.

17. Panelist, "Botox in the New Millennium: Look Young and Stay Dry." 10th Innovations in Urologic Practice, Santa Fe, NM, September 2002.

18. Panelist, "Neurourology 2003: State-of-the-Art Overactive Bladder." 10th Innovations in Urologic Practice, Santa Fe, NM, September 2002.

19. **"**ATP and Glutamate Release in the Spinal Cord During Increased Bladder Afferent Activity." Neuroscience Annual Meeting, Orlando, FL, November 2002.

20. "Botulinum Toxin A Improves Voiding and Pain Symptoms in a Patient with Interstitial Cystitis." The Second Annual Course of the International Society of Pelvic Neuromodulation, Phoenix, AZ, January 2003.

21. Panelist, "The Diagnosis and Treatment of Urge Incontinence: The Overactive Bladder." 98th American Urological Association Annual Meeting, Chicago, IL, May 2003

22. "Botulinum Toxin: A New Twist on "A" vs. "D." AUA National Meeting, Chicago, IL, 2003.

23. "Botulinum Toxin A Improves Voiding and Pain Symptoms in Patients with Interstitial Cystitis. A Case Series." Society of Female Urology and Neurourology Annual Meeting, Chicago, April 26, 2003.

24. "Changes in Spinal Cord Transmitter Release Patterns During Volume or Noxious Evoked Bladder Afferent Activity." Society of Female Urology and Neurourology Annual Meeting, Chicago, April 26, 2003.

25. "Effect of Stimulation Intensity and Botulinum Toxin Isoform on Rat Bladder Strip Contractions." Society of Female Urology and Neurourology Annual Meeting, Chicago, April 26, 2003.

26. Panelist, "Multiple Sclerosis and New Therapies." Society for Urodynamics and Female Urology Annual Meeting, Scottsdale, AZ, February 2004.

27. Panelist, "Urodynamic Evaluation of the Non-Neurogenic Male." 12th Innovations in Urologic Practice, Santa Fe, NM, September 2004.

28. "Increased Bladder Afferent Activation and Inflammation in a Genetic Model of Endogenous Adenosine Elevation." Society for Urodynamics and Female Urology Annual Meeting, Orlando, FL, 2005.

29. "Urine ATP and Adenosine Concentration Positively Correlate with Bother Score in Patients with Interstitial Cystitis." Society for Urodynamics and Female Urology Annual Meeting, Orlando, FL, 2005.

30. Panelist, "Neurotoxin and Desensitization Therapies for Voiding Dysfunction." AUA Annual Meeting, San Francisco, CA, May 2005.

31. "Increased Bladder Afferent Activation and Inflammation in a Genetic Model of Endogenous Adenosine Elevation." AUA Annual Meeting, 2005.

32. Panelist, "Future Developments in Botox as Pharmacomodulation." Society for Urodynamics and Female Urology (SUFU) and the International Society of Pelvic Neuromodulation (ISPiN) Annual Meeting, Grand Bahama Island, Bahamas, February 2006.

33. Panelist, "The Evolving Role of Botulinum Toxin: Application, Rationale, and Techniques in the Management of Voiding Dysfunction." Houston, TX, March 2006.

34. Panelist, "Controlling the Overactive Bladder: Pharmacologic And Neurotoxin Modulators." Beverly Hills, CA, March 2006.

35. Course Director, "The Evolving Role of Botulinum Toxin: Application, Rationale, and Techniques in the Management of Voiding Dysfunction." Chicago, IL, May 2006.

36. "Facilitated Purinergic Response in Normal Rat Bladders: Role Of Urothelium And Modulation By Endogenous Acetylcholine (ACh)." AUA Annual Meeting, 2006.

37. Panelist, "Botulinum Toxin and Desensitization Therapies for Voiding Dysfunction." AUA Annual Meeting, Atlanta, GA, May 2006.

38. Panelist, "Controlling the Overactive Bladder: Pharmacologic and Neurotoxin Modulators." Houston, TX, June 2006.

39. Panelist, "Botulinum Toxin and the Lower Urinary Tract." International Urogynecological Association Annual Meeting, Athens, Greece, September 2006.

40. Panelist, "Botox: Now and Beyond." 14th Innovations in Urologic Practice. Santa Fe, NM, September 2006.

41. Panelist, "Controlling the Overactive Bladder: Pharmacologic and Neurotoxin Modulators." Miami, FL, November 2006.

42. Panelist, "Interstitial Cystitis." A Multidisciplinary Approach to the Pelvis in 2006, The Methodist Hospital, Houston, TX, November 2006.

43. Panelist, "Evolving Understanding of Botulinum Neurotoxin Activity in the Genitourinary Tract." International Conference on Neurotoxins (ICON), Hollywood, FL, December 2006.

44. Course Director, "The Evolving Role of Botulinum Toxin: Application, Rationale, and Techniques in the Management of Voiding Dysfunction." Atlanta, GA, December 2006.

45. Moderator and Panelist, "Neuromodulation – Translational Research on BOTOX." Society for Urodynamics and Female Urology Annual Meeting, San Diego, CA, February 2007.

46. Panelist, "Managing Refractory Overactive Bladder Conditions: Translating the Pathophysiology of Refractory Conditions into Successful Management Outcomes." AUA Annual Meeting, Anaheim, CA, May 2007.

47. Faculty Director and Speaker, "New Options for Managing Urge Incontinence." American Urogynecological Society Annual Meeting, Hollywood, FL, September 2007.

48. Panelist, "Biological and Electrical Neuromodulators for the Treatment of Voiding Dysfunction." Los Angeles, CA, November 2007.

49. Course Director, "Use of Botox in OAB." Society of Mexican Urology Annual Meeting, Cancun, Mexico, November 2007.

50. Course Director, "Use of Botox in Urology." Society of Mexican Urology Annual Meeting, Cancun, Mexico, November 2007.

51. Panelist, "Neuromodulation and the Non-Neurogenic Bladder. Where Should it Be in the Algorithm for the Overactive Bladder." Update in Urogynecology and Female Urology, The University of Texas Medical School of Houston, Houston, TX, February 2008.

52. Panelist, Translational Research in Overactive Bladder. Society of Urodynamics and Female Urology Annual Meeting, Miami, FL, February 2008.

53. "Botox: Mechanism of Action." Society of Urodynamics and Female Urology Annual Meeting, Miami, FL, February 2008.

54. Panelist, Neurogenic Bladder. Society of Urodynamics and Female Urology Annual Meeting, Miami, FL, February 2008.

55. Panelist, "Diagnosis and Management of Refractory Overactive Bladder." 103rd Annual Meeting of the American Urological Association, Orlando, FL, May 2008.

56. Faculty, "Management of Refractory OAB." 16th Innovations in Urologic Practice, Santa Fe, NM, October 16-18, 2008.

57. Society for Urodynamics and Female Urology Annual Winter Meeting. Henderson, NV, February 25-28, 2009.

58. Anticoagulation Education for Prescribers. VA Employee Education System, May 6, 2009.

59. Faculty, "Botox Versus Minimally Invasive Treatments for BPH: Early Results of the MIST Trial." 17th Innovations in Urologic Practice. Houston, TX, October 2-3, 2009.

60. Faculty, "The Use of Botulinum Toxin in the Treatment of Lower Urinary Tract Disorders and Pelvic Floor Dysfunction" and "Pudendal Nerve Stimulation for the Treatment of IC/Chronic Pelvic Pain." 18th Innovations in Urologic Practice. Houston, TX, October 15-16, 2010.

61. Moderator, Basic Science Poster Session II. Speaker, "Bilateral Stimulation." Society for Urodynamics and Female Urology 2011 Winter Meeting. Phoenix, AZ, March 1-5, 2011.

62. Faculty, Symposium 2: "Refractory Bladder Pain Syndrome - Botulinum Toxin A Therapy." Japanese Urological Association Meeting, Washington, DC, May 15, 2011.

63. Faculty, "Managing Refractory Overactive Bladder Conditions: Translating the Patho-physiology of Refractory Conditions into Successful Management Outcomes." Office of Education Course 089IC. 106th Annual Meeting of the American Urological Association, Washington, DC, May 18, 2011.

64. Faculty Chair, "The Challenge of Neurogenic Bladder: New Approaches." Annenberg Center Symposium at Western Section of the American Urological Association: The Challenge of Neurogenic Bladder: New Approaches, Vancouver, BC, Canada, August 20-21, 2011.

65. Faculty, "Advances in the Use of Botulinum Toxin for Neurogenic Bladders." Paralyzed Veterans of America's Summit 2011 & Expo, Orlando, FL, September 17-18, 2011.

66. Faculty, "Advances in the Use of Botulinum Toxin for Neurogenic Bladders." Society for Urodynamics and Female Urology, 2012 Winter Meeting, New Orleans, LA, March 3, 2012.

67. Faculty, "Botulinum Toxin for Overactive Bladder." Baylor Urologic Innovations Update Conference, Houston, TX, May 14, 2012.

68. Moderator, "Voiding Dysfunction and Renal Transplant." 19th Innovations in Urologic Practice, Santa Fe, NM, October 5-7, 2012.

69. Faculty, "Botulinum Toxin and BPH: Results of the MIST Trial" and "Management of Refractory OAB." 19th Innovations in Urologic Practice, Santa Fe, NM, October 5-7, 2012.

70. Speaker, "Introduction to Use of Botulinum Neurotoxin for GU Conditions" and "Video and Pelvic Model Demonstrations." Workshop – Use of Botulinum Neurotoxin for GI/GU. TOXINS 2012: Basic Science and Clinical Aspects of Botulinum and Other Neurotoxins. Miami Beach, FL, December 5-8, 2012.

71. Faculty and Presenter, "Critical Discussion: Underactive Bladder and Chronic Urinary Retention in Older Adults." 109th Annual Meeting of the American Urological Association, Meeting Plenary Program. Orlando, FL, May 16-21, 2014.

C. **Publications**:

1. **Full Papers**:

a. **Published in Peer-Reviewed Journals**:

1. **Smith CP**, Kraus SR, Boone TB: Management of impending penile prosthesis erosion with polytetrafluoroethylene distal wind sock graft. J Urol 160:2037, 1998.

2. **Smith CP**, Sharma A, Ayala G, Cagle P, Kadmon D: Solitary pulmonary metastasis from prostate cancer. J Urol 162:2102, 1999.

3. Duchene DA, **Smith CP**, Goldfarb RA: Allopurinol induced meningitis. J Urol 164(6):2028, 2000.

4. Kim IY, **Smith C**, Oliver J, Lapin SL: Bacillus Calmette-Guerin induced peritonitis in a patient on dialysis. J Urol 163:237, 2000.

5. **Smith CP**, Kraus SR, Nickell KG, Boone TB: Videourodynamic findings in men with Central Cord Syndrome. J Urol 164(6):2014-2017, 2000.

6. Yoshimura N, **Smith CP**, Chancellor MB, de Groat WC: Pharmacologic and potential biologic interventions to restore bladder function after spinal cord injury. Curr Opin Neurol 13:677, 2000.

7. Sasaki K, **Smith CP,** Chuang YC, Lee JY, Kim JC, Chancellor MB: Oral gabapentin (neurontin) treatment of refractory genitourinary tract pain. Tech Urol 7(1):47-49, 2001.

8. **Smith CP**, Chancellor MB: Genitourinary tract patent update. Exp Opin Ther Patents 11(1):1-15, 2001.

9. **Smith CP,** Somogyi GT, Bird ET, Chancellor MB, Boone TB: Neurogenic bladder model for spinal cord injury: Spinal cord microdialysis and chronic urodynamics. Brain Res Brain Res Protoc 9(1):57-64, 2002 [PMID: 11852271].

10. O'Leary ML, **Smith CP,** Erickson J, Somogyi GT and Chancellor MB: Botulinum toxin urethral sphincter injection to restore bladder emptying in a woman with multiple sclerosis. Int J MS Care 4:70-72, 2002.

11. Chung SY, Franks M, **Smith CP,** Lee JY, Lu SH, Chancellor MB: Technique of combined pubovaginal sling and cystocele repair using a single piece of cadaveric dermal graft. Urology 59(4):538-541, 2002.

12. O'Leary ML, **Smith CP,** Erickson JR, Eidelman BH, Chancellor MB: Neurovesical dysfunction in postural tachycardia syndrome (POTS). Int Urogynecol J Pelvic Floor Dysfunct 13(2):139-140, 2002.

13. **Smith CP,** Somogyi GT, Chancellor MB: Botulinum toxin treatment of urethral and bladder dysfunction. Int Braz J Urol 28(6):545-552, 2002.

14. Lu SH, Yamagata T, Atsuki K, Sun L, **Smith CP,** Yoshimura N, Chancellor MB, de Groat WC: Effect of KW-7158, a putative afferent nerve inhibitor, on bladder and vesico-vascular reflexes in rats. Brain Res 946(1):72-78, 2002.

15. O'Leary M, Erickson JR, **Smith CP,** Cannon TW, Fraser M, Boyd M, Heyman R, Chancellor MB: Changes in voiding patterns in patients with MS and extended-release oxybutynin. Int J MS Care 4(3):116-119, 2002.

16. **Smith CP,** O'Leary M, Erickson J, Somogyi GT, Chancellor MB: Botulinum toxin urethral sphincter injection resolves urinary retention after pubovaginal sling operation. Int Urogynecol J Pelvic Floor Dysfunct 13(3):185-186, 2002.

17. Franks ME, Zyczynski HM, Moalli P, Sagan ER, **Smith CP,** Cannon T, Chancellor MB: Clinical outcome and cost comparison with the pubovaginal sling procedure using autologous fascia versus cadaveric dermal patch. J Pelvic Surgery 8(1):19-22, 2002.

18. Somogyi GT, Yokoyama T, Szell EA, **Smith CP**, de Groat WC, Huard J, Chancellor MB: Effect of cryoinjury on the contractile parameters of bladder strips: A model of impaired detrusor contractility. Brain Res Bull 59(1):23-28, 2002.

19. **Smith CP,** Somogyi GT, Chancellor MB: Emerging role of botulinum toxin in the treatment of neurogenic and non-neurogenic voiding dysfunction. Curr Urol Rep 3(5):382-387, 2002.

20. Yokoyama T, Kumon H, **Smith CP**, Somogyi GT, Chancellor MB: Botulinum toxin treatment of urethral and bladder dysfunction. Acta Med Okayama 56(6):271-277, 2002.

21. Somogyi GT, Zernova GV, Yoshiyama M, Rocha JN, **Smith CP**, de Groat WC: Change in muscarinic modulation of transmitter release in the rat urinary bladder after spinal cord injury. Neurochem Int 43(1):73-77, 2003.

22. **Smith CP**, Franks ME, McNeil BK, Ghosh R, de Groat WC, Chancellor MB, Somogyi GT: Effect of botulinum toxin A on the autonomic nervous system of the rat lower urinary tract. J Urol 169(5):1896-1900, 2003 [PMID: 12686869].

23. **Smith CP**, Boone TB, de Groat WC, Chancellor MB, Somogyi GT: Effect of stimulation intensity and botulinum toxin isoform on rat bladder strip contractions. Brain Res Bull 61(2):165-171, 2003 [PMID: 12832003].

24. O'Leary, M, Erickson, JR, **Smith CP**, McDermott C, Horton J, Chancellor MB: Effect of controlled-release oxybutynin on neurogenic bladder function in spinal cord injury. J Spinal Cord Med 26(2):159-162, 2003.

25. Chuang YC, **Smith CP**, Somogyi GT, Chancellor MB: Botulinum toxin treatment of urethral and bladder dysfunction. J Formos Med Assoc 102(1):5-11, 2003.

26. Lai, HH, **Smith CP**, Teh BS, Butler EB, Boone TB: Pelvic radiotherapy does not increase the complication rates of artificial urinary sphincter implantation. Int J Radiat Oncol Biol Phys 57(2 Suppl):S273, 2003.

27. Cannon TW, Lee JY, Somogyi G, Pruchnic R, **Smith CP**, Huard J, Chancellor MB: Improved sphincter contractility after allogenic muscle-derived progenitor cell injection into the denervated rat urethra. Urology 62(5):958-963, 2003.

28. **Smith CP**, Chancellor MB: Emerging role of botulinum toxin in the treatment of voiding dysfunction. J Urol 171:2128-2137, 2004 [PMID: 15126771].

29. Khera M, Somogyi GT, Kiss S, Boone TB, **Smith CP**: Botulinum toxin-A inhibits ATP release from bladder urothelium after chronic spinal cord injury. Neurochem Int 45(7):987-993, 2004 [PMID: 15337297].

30. Khera M, Boone TB, **Smith CP**: Botulinum toxin A: A novel approach in the treatment of recurrent urethral strictures. J Urol 172(2):574-575, 2004 [PMID: 15247734].

31. **Smith CP**, Radziszewski P, Borkowski A, Somogyi GT, Boone TB, Chancellor MB: Botulinum toxin-A has antinociceptive effects in treating interstitial cystitis. Urology 64(5):871-875, 2004 [PMID: 15533466].

32. **Smith CP**, Somogyi GT, Chancellor MB, Appell RA: A case for botulinum toxin-A in idiopathic bladder overactivity. Curr Urol Rep 5(6):432-436, 2004.

33. Lai HH, Boone TB, Yang G, **Smith CP**, Kiss S, Thompson TC, Somogyi GT: Loss of caveolin-1 expression is associated with disruption of muscarinic cholinergic activities in the urinary bladder. Neurochem Int 45(8):1185-1193, 2004.

34. **Smith CP**, Somogyi GT, Boone TB: Botulinum toxin in urology: Evaluation using an evidence-based medicine approach. Nat Clin Pract Urol 1(1):31-38, 2004.

35. Vemulakonda VM, Somogyi GT, Kiss S, Salas N, Boone TB, **Smith CP**: Inhibitory effect of intravesically applied botulinum toxin A in chronic bladder inflammation. J Urol 173(2):621-624, 2005 [PMID: 15643276].

36. **Smith CP**, Nishiguchi J, O'Leary M, Yoshimura N, Chancellor MB: Single institution experience in 110 patients with botulinum toxin A injection into the bladder or urethra. Urology 65(1):37-41, 2005 [PMID: 15667859].

37. Khera M, Somogyi GT, Salas NA, Kiss S, Boone TB, **Smith CP**: *In vivo* effects of botulinum toxin A on visceral sensory function in chronic spinal cord-injured rats. Urology 66(1):208-212, Jul 2005 [PMID: 15992889].

38. Chancellor MB, **Smith CP**: Pittsburgh experience with lower urinary tract botulinum toxin A injection. Curr Urol Rep 6(4):235-236, Jul 2005.

39. **Smith CP**, Vemulakonda VM, Kiss S, Boone TB, Somogyi GT: Enhanced ATP release from rat bladder urothelium during chronic bladder inflammation: Effect of botulinum toxin A. Neurochem Int 47(4):291-297, Sep 2005 [PMID: 15970360].

40. **Smith CP**, Chancellor MB: Simplified bladder botulinum-toxin delivery technique using flexible cystoscope and 10 sites of injection. J Endourol 19(7):880-882, Sep 2005 [PMID: 16190850].

41. **Smith CP**: Botulinum toxin for overactive bladder: Reaching a happy median. Nat Clin Pract Urol 3(3):128-129, Mar 2006.

42. Salas NA, Somogyi GT, Gangitano DA, Boone TB, **Smith CP**: Receptor activated bladder and spinal ATP release in neurally intact and chronic spinal cord injured rats. Neurochem Int 50(2):345-350, Jan 2007.

43. Lai HH, Boone TB, Thompson TC**, Smith CP**, Somogyi GT: Using caveolin-1 knockout mouse to study impaired detrusor contractility and disrupted muscarinic activity in the aging bladder. Urology 69(2):407-411, Feb 2007.

44. Smith PP, **Smith CP**, Boone TB, Somogyi GT: Is abdominal wall contraction important for normal voiding in the female rat? BMC Urol 7:5, Mar 2007.

45. Lemack GE, Amundsen C, Badlani G, Griebling T, Peters K, Rodriguez L, Singla A, **Smith C**, Sullivan M, Te A: Highlights from the combined Society of Urodynamics and Female Urology, and International Society of Pelvic Neuromodulation annual meeting. J Urol 177(2):691-695, Feb 2007.

46. Smith PP, Hurtado E, **Smith CP**, Boone TB, Somogyi GT: Comparison of cystometric methods in female rats. Neurourol Urodyn, Sep 11, 2007.

47. Lai HH, **Smith CP**: Hitting below the belt (bladder): Botulinum treatment of urethral and prostate disorders. Curr Urol Rep 8(5):351-358, Sep 2007.

48. **Smith CP**, Gangitano DA, Munoz A, Salas NA, Boone TB, Aoki KR, Francis J, Somogyi GT: Botulinum toxin type A normalizes alterations in urothelial ATP and NO release induced by chronic spinal cord injury. Neurochem Int 52(6):1068-1075, 2008 [PMID: 18187233].

49. Chancellor MB, Fowler CJ, Apostolidis A, de Groat WC, **Smith CP**, Somogyi GT, Aoki KR: Drug insight: Biological effects of botulinum toxin A in the lower urinary tract. Nat Clin Pract Urol 5:319-328, 2008 [PMID: 18461049].

50. Lai HH, **Smith CP**, Munoz A, Boone TB, Szigeti GP, Somogyi GT: Activation of cholinergic receptors blocks non-adrenergic non-cholinergic contractions in the rat urinary bladder. Brain Res Bull 77:420-426, 2008.

51. **Smith CP**: Botulinum toxin in the treatment of OAB, BPH, and IC. Toxicon 54:639-646, 2009 [PMID: 19268490].

52. Munoz A, Gangitano DA, **Smith CP**, Boone T, Somogyi GT: Removal of urothelium affects bladder contractility and ATP but not release of NO in rat urinary bladder. BMC 10:10-16, 2010 [PMID: 20497558].

53. Starkman JS, **Smith CP**, Staskin DR: Surgical options for drug-refractory overactive bladder patients. Rev Urol 12(2-3):e97-e110, Spring 2010 [PMID: 20811558].

54. **Smith CP**, Sorrells A, Coburn M: Management of urinary retention in an austere environment: Suprapubic catheter placement. J Spec Oper Med 10(3):36-40, Summer 2010 [PMID: 21049433].

55. **Smith CP**: Botox® in urology – Will it become standard of care for urge urinary incontinence? J Urol 184(6):2235-2236, Dec 2010 [PMID: 20952015].

56. Munoz A, **Smith CP**, Boone TB, Somogyi GT: Overactive and underactive bladder dysfunction is reflected by alterations in urothelial ATP and NO release. Neurochem Int 58(3):295-300, Feb 2011 [PMID: 21145365].

57. Munoz A, Somogyi GT, Boone TB, **Smith CP**: Central inhibitory effect of intravesically applied botulinum toxin A in chronic spinal cord injury. Neurourol Urodyn 30(7):1376-1381, Sep 2011 [PMID: 21509809].

58. Lai HH, Munoz A, **Smith CP**, Boone TB, Somogyi GT: Plasticity of non-adrenergic non-cholinergic bladder contractions in rats after chronic spinal cord injury. Brain Res Bull 86(1-2):91-96, Aug 2011 [PMID: 21689735].

59. Crawford ED, Hirst K, Kusek JW, Donnell RF, Kaplan SA, McVary KT, Mynderse LA, Roehrborn CG, **Smith CP**, Bruskewitz R: Effects of 100 and 300 units of onabotulinum toxin A on lower urinary tract symptoms of benign prostatic hyperplasia: A phase II randomized clinical trial. J Urol 186(3):965-970, Sep 2011 [PMID: 21791356].

60. Munoz A, Somogyi GT, Boone TB, **Smith CP**: Lumbosacral sensory neuronal activity is enhanced by activation of urothelial purinergic receptors. Brain Res Bull 25:86(5-6):380-384, Nov 2011 [PMID: 21924327].

61. Munoz A, Somogyi GT, Boone TB, Ford AP, **Smith CP**: Modulation of bladder afferent signals in normal and spinal cord-injured rats by purinergic P2X3 and P2X2/3 receptors. BJU Int 110(8 Pt B):E409-414, Oct 2012 [PMID: 22540742].

62. Esquenazi A, Albanese A, Chancellor MB, Elovic E, Segal KR, Simpson DM, **Smith CP**, Ward AB: Evidence-based review and assessment of botulinum neurotoxin for the treatment of adult spasticity in the upper motor neuron syndrome. Toxicon 67:115-128, Jun 2013 [PMID: 23220492].

63. Boone TB, **Smith CP**, Munoz A: Diabetic plasticity of non-adrenergic non-cholinergic and P2X-mediated rat bladder contractions. Brain Res Bull 95:40-45, Jun 2013 [PMID: 23562604].

64. Chancellor MB, Elovic E, Esquenazi A, Naumann M, Segal KR, Schiavo G, **Smith CP**, Ward AB: Evidence-based review and assessment of botulinum neurotoxin for the treatment of urologic conditions. Toxicon 67:129-140, Jun 2013 [PMID: 23415704].

65. Jimenez-Cidre M, Costa P, Ng-Mak D, Sahai A, Degboe A, **Smith CP**, Tsai K: Assessment of treatment-seeking behavior, and healthcare utilization in an international cohort of subjects with overactive bladder. Curr Med Res Opin, published online (http://informahealthcare.com/doi/full/10.1185/03007995.2014.918028) p 1-8, May 2014; 30(8):1557-1564, Aug 2014 [PMID: 24762033].

b. **Accepted or In Press**:

1. Scovell JM, Chan R, **Smith CP**: Transurethral use of a nephroscope significantly aids in the surgical management of an intrauterine device eroding into the bladder. Female Pelvic Med Reconstr Surg, accepted for publication Apr 2014.

2. **Other Full Papers**:

a. **Published Without Review by Peer Group**:

1. **Smith CP**, Kraus SR, Boone TB: Urinary retention in the female. AUA Update Series, Volume XVIII, Lesson 19, 1999.

2. Kraus SR, **Smith CP**, Boone TB: Primary bladder neck obstruction in the male. AUA Update Series, Volume XIX, Lesson 8, 2000.

3. **Smith CP**, Somogyi GT, Chancellor MB: Poisoning the spastic bladder and urethra. Reviews in Urology 4:61-68, 2002.

4. **Smith CP,** Somogyi GT: Update on use of botulinum toxin to treat overactive bladder. Current Bladder Dysfunction Reports 2:65-70, 2007.

5. **Smith CP**, Chancellor MB: Botulinum toxin: Clinical uses in the lower urinary tract. AUA Update Series, Volume 27, Lesson 15, 2008.

6. **Smith CP**: Botox (onabotulinumtoxinA) pivotal data. Botox (onabotulinumtoxinA) for the treatment of urinary incontinence due to neurogenic detrusor overactivity in patients who have an inadequate response to or are intolerant of an anticholinergic. Urology Times (Supplement), Dec 2012.

b. **In Preparation**: Not Applicable

3. **Abstracts Given During the Last Three Years**:

1. Munoz A, Somogyi GT, Boone TB, Ford AP, **Smith CP**: Inhibition of P2X2/3 purinergic receptors diminishes lumbosacral neuronal activity to mechanical or chemical bladder stimulation. Abstract #210, Moderated Poster. Presented at the 106th Annual Meeting of the American Urological Association, Washington, DC, May 14-19, 2011.

2. Munoz A, Somogyi GT, Boone TB, **Smith CP**: Lumbosacral neuronal activity is enhanced from activation of urothelial purinergic receptors. *Best Poster Award*: Abstract #218, Moderated Poster. Presented at the 106th Annual Meeting of the American Urological Association, Washington, DC, May 14-19, 2011.

3. Mengheang L, Hairston J, **Smith CP**: Efficacy of onabotulinumtoxina in patients with neurogenic bladder and decreased bladder compliance. Abstract #1517, Moderated Poster. Presented at the 106th Annual Meeting of the American Urological Association, Washington, DC, May 14-19, 2011.

4. Yao Chi Chuang YC, Huang CC, **Smith CP**, Somogyi G, Kaufman J, Nirmal J, Tyagi P, Chancellor M: Liposomes enhance therapeutic efficiency of intravesical tacrolimus by increased drug exposure. Abstract 37. Urodynamics/Incontinence/Female Urology: Basic Research I, Moderated Poster (Moderator: **Smith CP**). Presented at the 107th Annual Meeting of the American Urological Association, Atlanta, GA, May 19-24, 2012.

5. Munoz A, **Smith CP**, Boone TB, Somogyi G: Altered P2X signaling reduces nitric oxide production in the diabetic urothelium. Abstract 261. Bladder and Urethra: Anatomy, Physiology and Pharmacology I, Moderated Poster. Presented at the 107th Annual Meeting of the American Urological Association, Atlanta, GA, May 19-24, 2012.

6. Munoz A, Somogyi G, Boone TB, Ford A, **Smith CP**: Modulation of bladder afferent signals in normal and spinal cord injured rats by P2X3 and P2X2/3 purinergic receptors. Abstract 62. Bladder and Urethra: Anatomy, Physiology and Pharmacology I, Moderated Poster. Presented at the 107th Annual Meeting of the American Urological Association, Atlanta, GA, May 19-24, 2012.

7. Au JK, Florentin D, Ding Y, He D, Creighton CJ, Frolov A, Dakhova O, Zhang Y, **Smith CP**, Kadmon D, Miles BJ, Ittmann M, Rowley D, Ayala G: Abstract 313. Influence of the neural microenvironment in prostate cancer. Prostate Cancer: Basic Research II, Moderated Poster. Presented at the 107th Annual Meeting of the American Urological Association, Atlanta, GA, May 19-24, 2012.

8. Ayala G, Florentin D, Au JK, Ding Y, He D, Creighton CJ, Frolov A, Dakhova O, Zhang Y, **Smith CP**, Kadmon D, Miles BJ, Ittmann, M: Targeting the neural microenvironment in prostate cancer: A neoadjuvant Botox clinical trial. Abstract 1633. Prostate Cancer: Localized VIII, Moderated Poster. Presented at the 107th Annual Meeting of the American Urological Association, Atlanta, GA, May 19-24, 2012.

9. Jimenez-Cidre M, Costa P, Globe D, Ng-Mak D, Sahai A, **Smith C**, Tsai K, Herschorn S: International burden of incontinence study: Association between incontinence severity and healthcare utilization. Abstract 14997. Non-Discussion Poster. Presented at the 43rd Annual Meeting of the International Continence Society, Barcelona, Spain, Aug 26-30, 2013.

4. **Books**:

a. **Complete Books Written**:

1. Chancellor MB, **Smith CP**: *Botulinum Toxin in Urology*. First Edition. New York: Springer, Aug 2011.

b. **Books Edited**: Not Applicable

c. **Book Chapters Written**:

1. **Smith CP,** Boone TB: Pitfalls and artifacts in urodynamic studies. In *Practical Urodynamics*. Edited by V Nitti. Philadelphia: WB Saunders, 1998.

2. **Smith CP,** Chancellor MB: Neurourology. In *Fast Facts-Urology Highlights* 1999-2000. Edited by J Shah. Abingdon, Oxford: Health Press Limited, 2000.

3. **Smith CP,** Chancellor MB: Neurourology. In *Fast Facts-Urology Highlights* 2000-2001. Edited by J Shah. Abingdon, Oxford: Health Press Limited, 2001.

4. **Smith CP**, Blaivas JG, Chancellor MB: Lower urinary tract dysfunction in the male. In *Pelvic Floor Disorders*. Edited by AP Bourcier, EJ McGuire, P Abrams. Philadelphia: Saunders Elsevier, 2004.

5. Dykstra D, Schurch B, **Smith CP**, Chancellor MB: Botulinum toxin in the treatment of urologic disorders. 2006.

6. Kim DK, Thomas C, **Smith C**, Chancellor MB: The case for bladder botulinum toxin application. Urol Clin North Am 33(4):503-511, 2006.

7. **Smith CP**, Somogyi GT: Botulinum toxin. In *Overactive Bladder*. Edited by R Dmochowski, K Kreder. London: Informa Healthcare, 2007.

8. Smith PP, **Smith CP**: Botulinum toxin in the treatment of chronic pelvic pain syndromes. In *Botulinum Toxin: Therapeutic Clinical Practice and Science.* Edited by J Jankovic, M Hallett, NH Mayer, JO Dolly, A Albanese. Philadelphia: Elsevier, Inc, 2008.

9. Chancellor MB, Somogyi GT, **Smith CP:** Mechanism of action of botulinum neurotoxin in the genitourinary tract. In *Botulinum Toxin: Therapeutic Clinical Practice and Science.* Edited by J Jankovic, M Hallett, NH Mayer, JO Dolly, A Albanese. Philadelphia: Elsevier, Inc, 2008.

10. Lai HH, **Smith CP**, Boone TB: Urodynamic evaluation. In *Female Urology*, 3rd Edition. Section 2: Evaluation and Diagnosis, Chapter 11. Edited by S Raz, L Rodriguez. Philadelphia: Saunders Elsevier, 2008.

11. Smith PP, **Smith CP**: Urinary tract infections. In *Urology and the Primary Care Practitioner*, 3rd Edition, Chapter 4. Edited by LI Lipshultz, M Khera, DT Atwal DT. Philadelphia, PA: Elsevier, Dec 2008, pp 47-60.

12. Smith PP, **Smith CP**: Botulinum toxin in the treatment of chronic pelvic pain syndromes. In *Botulinum Toxin: Therapeutic Clinical Practice and Science*. Edited by J Jankovic, M Hallett, NH Mayer, *et al*. Philadelphia: Elsevier, Inc, 2009.

13. Chancellor MB, Somogyi GT, **Smith CP**: Mechanism of action of botulinum neurotoxin in the genitourinary tract. In *Botulinum Toxin: Therapeutic Clinical Practice and Science*. Edited by J Jankovic, M Hallett, NH Mayer, *et al*. Philadelphia: Elsevier, Inc, 2009.

14. **Smith, CP**: Intravesical pharmacologic treatment for neurogenic detrusor overactivity. In *Textbook of the Neurogenic Bladder*, Third Edition, Chapter 45. Edited by J Corcos, D Ginsberg, G Karsenty. Informa Healthcare USA, in press, to be published Aug 15, 2015.

5. **Other Works Communicating Research Results to Scientific Colleagues**: Not Applicable

6. **Other Works Communicating Research Results to General Public**: Not Applicable

III. TEACHING INFORMATION

A. Didactic Course Work:

1. Courses Taught at BCM Within the Primary Department:

2002-Present Reading Group Mentor

2. Courses Taught at BCM External to the Primary Department:

2002-Present "Autonomic Pharmacology Lecture." Baylor College of Medicine, Pharmacology lecture to medical students on quarterly basis, Houston, TX

2009-Present Instructor, Surgical Subspecialty Lectures, Medical Students, Baylor College of Medicine, Houston, TX

3. Courses Taught at Other Institutions While at BCM:

1. "Botox in the New Millennium: Look Young and Stay Dry." 10th Innovations in Urologic Practice, Sante Fe, NM, September 2002.

2. "Neurourology 2003: State of the Art Overactive Bladder." 10th Innovations in Urologic Practice, Sante Fe, NM, September 2002.

B. Curriculum Development Work:

2003-2006	Baylor College of Medicine Curriculum Competency Subcommittee Member
2002-Present	Reading Group for Urology Residents
2006-Present	Residency Review Committee

C. Non-Didactic Teaching While at BCM:

1. Resident Training:

<u>1-Year Laboratory Training for 4th Year Urologic Residents</u>

2002	H. Henry Lai, M.D.
2003	Mohit Khera, M.D.
	Vijaya Vemulakonda, M.D.
	Jeffrey Evans. M.D.
2004	Kimberley Takahashi, M.D.
2005	Elias Hsu, M.D.
2006	Desiderio Avila, M.D.
	John Boon, M.D.
2007	Zaneta Romain, M.D.
	Kenneth Yun, M.D.
	Samson Shen, M.D.
	Melina McCarty, M.D.

2003	H. Henry Lai, M.D., received a second place of the Lapides Award for his work on role of caveoline in the bladder function
2005	H. Henry Lai, M.D., received a 1-year AFUD fellowship for pursuing 1 year research in the Neurourology Laboratory in the Scott Department of Urology
2006	Elias Hsu, M.D., received the Arnold's award as the best resident researcher in 2005-2006
2006	Mohit Khera, M.D., received the AFUD fellowship and Pfizer Award for 2006-2007
2004-Present	Faculty Mentor for Medicine residents participating in the Woman's Health Initiative for LACE program

2. **Clinical Fellow Training**:

2003-2006	Rebecca McCrery, M.D., Urogynecology Fellow in Neurourology and Female Urology
2004-2007	Phillip P. Smith, M.D., Urogynecology Fellow in Neurourology and Female Urology
2005-2007	Henry H. Lai, M.D., Urology Fellow in Neurourology and Female Urology
2005-2008	Eric Hurtado, M.D., Urogynecology Fellow in Neurourology and Female Urology

3. **Research Fellow Training**:

<u>1-Year Laboratory Training</u>:

2004	Rebecca McCrery, M.D.
2005	Phillip P. Smith, M.D.
	Zachary Zuniga, M.D.
	H. Henry Lai, M.D. (AFUD Fellowship)
2006	Eric Hurtado, M.D.
	Mohit Khera, M.D. (AFUD Fellowship)

4. **Graduate Student Training**:

2005-2006	H. Henry Lai, M.D., AFUD Scholar Fellowship
2006-2007	David Gangitano, Ph.D., Postdoctoral Fellow
2007-2008	Alvaro Munoz, Ph.D., Postdoctoral Fellow

5. **Medical Student Training**:

<u>1-2 Months Research Laboratory Rotation</u>:

2003 Rahmat Ali (July-August - 2 months), University of Karachi

2004	Jennifer Sung	2nd year (March, 1 month), Baylor College of Medicine (BCM)
	Vairavan Subramanian	4th year (April-May, 2 months), Baylor College of Medicine
	Tulika Garg	4th year (June-July, 2 months), Baylor College of Medicine
	Brenda Tharian	2nd year (July, 1 month), Texas A&M
2005	Catherine Chen	2nd year (March 1-30) BCM
	Joe Kuebeker	3rd year (April 1-May 10) BCM
	Samir Shirodkar	3rd year (May 11-June 30) BCM
	Philip Ho	3rd year (Aug 29-Sep 23) BCM
2006	David Goldfarb	3rd year (January 3-31), BCM
	Jeff Walter	3rd year (March 2-28), BCM

D. **Lectures**: Included in II. B.4. Invited Lectures, Presentations, Research Seminars

1. International: See II. B.4. Invited Lectures, Presentations, Research Seminars
2. National: See II. B.4. Invited Lectures, Presentations, Research Seminars
3. Regional: See II. B.4. Invited Lectures, Presentations, Research Seminars
4. Local: See II. B.4. Invited Lectures, Presentations, Research Seminars

E. **Visiting Professorships**: Not Applicable

IV. MEDICAL AND SERVICE INFORMATION

A. **Patient Care Responsibilities at BCM and/or its Affiliated Institutions**:

1. **Department-wide**: Not Applicable
2. **Section or Specialty**: Not Applicable

B. **Clinical Laboratory Responsibilities at BCM**: Co-Director of Neurourology Laboratory

C. **National Education or Voluntary Health Organization Participation**:

2003-2005	Board Member, Interstitial Cystitis United of Texas
2005-Present	Medical Advisory Board Member, Interstitial Cystitis United of Texas
2002-Present	Presentations on Voiding Dysfunction for local Multiple Sclerosis Societies, ICU of Texas, and Parkinson Foundation of Harris County
2002-Present	Presentations on Voiding Dysfunction at Brentwood Baptist Church, Houston, TX

D. **Administrative Assignments at BCM**:

1. **Department Administration/Committees**:

2005-Present	Education Committee

2. **College Administration/Committees**:

2003-2006	Baylor Admissions Committee
2003-2006	Baylor Curriculum Competency Subcommittee
2006-Present	Baylor Residency Review Committee

2004-Present	Baylor Woman's Health Initiative Rotation for Internal Medicine Residents
2011-Present	The Institutional Review Board for Human Subject Research for BCM and Affiliated Hospitals: Board 2
2012-Present	Urology Safety Officer, Baylor ACE Council

E. **Other Pertinent Information Not Given Above**:

1. **Hospital Appointments**:

2004-Present	The Methodist Hospital Main Operating Room Subcommittee, Houston, TX

2. **Consultant Appointments**:

1. Allergan USA, Inc.: Member, Advisory Board

3. **TV Interviews**:

1. "Use of Botulinum Toxin for OAB and Interstitial Cystitis." Channel 2 TV, Houston, TX, April 2003.

2. "Botox for OAB and Interstitial Cystitis." Baylor TV Healthline, Baylor College of Medicine, Houston, TX, April 2003.

3. "Trials Begin for New Botox Bladder Treatment." FoxNews 26, Houston, TX, November 20, 2007.

4. "Ask the Doctor: Treating an Overactive Bladder." FoxNews 26, Houston, TX, July 22, 2008.

4. **Media - Internet**:

1. Held Hostage by the Bladder. News Channel 5, WPTV.com, Jacksonville, FL, October 12, 2010. (http://www.wptv.com/dpp/about_us/as_seen_on/held-hostage-by-the-bladder)

2. Doctor Implants Device to Control Overactive Bladder. News Channel 5, WTVF-TV, Nashville, TN, October 26, 2010. (http://www.newschannel5.com/Global/story.asp?S=13390685)

3. Ginsberg DA, Kennelly MJ, **Smith CP**: Managing Patients With Neurogenic Bladder: Expert Insights for Optimizing Patient Outcomes. Web-based CME Presentation, August 17, 2011. (http://www.medscape.org/viewarticle/747816)

A Double-Blind, Randomized Study of Safety and Efficacy of OnabotulinumtoxinA (OnaBoNT-A) versus Oral Oxybutynin in SCI Patients with NDO (11-09-10-04)

SC110198; SCIRP-CTA-R

W81XWH-12-1-0549

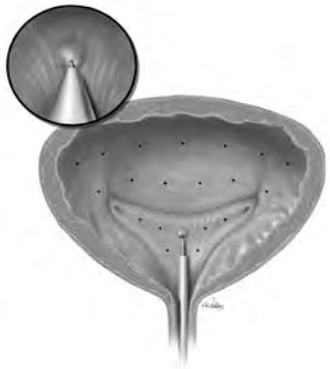
PI: Christopher P. Smith, MD **Org:** Baylor College of Medicine **Award Amount:** 904,516.00

Study/Product Aim(s)

- Screen, enroll, and treat 36 patients randomized to two treatment groups
- Evaluation of biomarkers pretreatment and during follow up

Approach

FDA IND, BCM IRB, and MEDVAMC approvals were granted. HPRO approval with funding notice was received March 2013. IRB/VA approvals for advertising were approved. Continue to recruit at MEDVAMC and start recruitment at The Institute of Rehabilitation and Research (TIRR), located in the Texas Medical Center by end of 2014.



BOTOX Injection Pattern Diagram

Accomplishment: Letters (257) have been mailed to patients. One subject consented but lost to follow-up prior to treatment. 130 charts have been reviewed with no patients accrued. Dr. Smith has completed training to acquire certification at new site, TIRR Memorial Hermann and is awaiting committee approval. Then patient accrual at TIRR can commence.

Timeline and Cost

Activities FY	12	13	14	15	16
Regulatory Approvals					
Screening, Enrollment, Treatment					
Biomarker Evaluation					
Follow-up Visits					
Data Analysis/Reporting					
Estimated Budget ($K)	81	356	360	349	NCE

Updated: October 2014

Goals/Milestones

CY12 Goal – Regulatory Affairs

☑ All required approvals are in place

CY13 Goals – Enrollment

☑ Advertisements have been placed and patient letters have been mailed

CY14 Goal – Subject visits and biomarker evaluations

☑ Accrual goals not met. We will expand recruitment base to include another hospital with a large spinal cord population, TIRR.

CY15 Goal – Accrual continuing

☐ Subject recruitment and follow-up visits , biomarker evaluation, and Data analysis/reporting completed

CY16 Goal – Accrual continuing

☐ Subject recruitment and follow-up visits , biomarker evaluation, and Data analysis/reporting completed

Comments/Challenges/Issues/Concerns

- Delayed enrollment due to BCM IRB/VA and TIRR/Memorial Hermann approvals

Budget Expenditure to Date

Projected Expenditure: $85,000

Actual Expenditure: $82.693